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Supreme Court of the United States

October Term, 1995

WILLIAM DAUBERT AND JOYCE DAUBERT,
INDIVIDUALLY AND AS GUARDIANS AD LITEM
FOR JASON DAUBERT, AND ANITA DE YOUNG,
INDIVIDUALLY AND AS GUARDIAN AD LITEM
FOR ERIC SCHULLER,

Petitioners,

v.

MERRELL DOW PHARMACEUTICALS, INC.,

Respondent.

PETITION FOR WRIT OF CERTIORARI TO THE
UNITED STATES COURT OF APPEALS FOR THE NINTH CIRCUIT

APPENDIX TO PETITION FOR WRIT OF CERTIORARI

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APPENDIX A

UNITED STATES COURT OF APPEALS
For the Ninth Circuit

No. 90-55397

WILLIAM DAUBERT; JOYCE DAUBERT, individually and as Guardians Ad Litem for JASON DAUBERT, a minor; ANITA DE YOUNG, individually, and As Guardian Ad Litem for ERIC SCHULLER,

Plaintiffs-Appellants,

v.

MERRELL DOW PHARMACEUTICALS, INC., a Delaware corporation,

Defendant-Appellee.

Appeal from the United States District Court
For the Southern District of California

March 22, 1994, Argued, Submitted,
San Francisco, California

January 4, 1994, Filed

Before: Alex Kozinski and Diarmuid F. O'Scannlain, Circuit Judges, and Stephen M. McNamee,* District Judge.

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* The Honorable Stephen M. McNamee, United States District Judge for the District of Arizona, sitting by designation.

KOZINSKI, Circuit Judge.

On remand from the United States Supreme Court, we undertake "the task of ensuring that an expert's testimony both rests on a reliable foundation and is relevant to the task at hand." Daubert v. Merrell Dow Pharmaceuticals, Inc., 125 L. Ed. 2d 469, 113 S. Ct. 2786, 2799 (1993).

I

A. Background

Two minors brought suit against Merrell Dow Pharmaceuticals, claiming they suffered limb reduction birth defects[1] because their mothers had taken Bendectin, a drug prescribed for morning sickness to about 17.5 million pregnant women in the United States between 1957 and 1982. *See* Resp't's Br. on Writ of Cert. at 2; *Turpin v. Merrell Dow Pharmaceuticals, Inc.*, 959 F.2d 1349, 1350 (6th Cir. 1992). This appeal deals with an evidentiary question: whether certain expert scientific testimony is admissible to prove that Bendectin caused the plaintiffs' birth defects.

For the most part, we don't know how birth defects come about. We do know they occur in 2-3% of births, whether or not the expectant mother has taken Bendectin. *See* Jose F. Cordero & Godfrey P. Oakley, Jr., Drug Exposure During Pregnancy: Some Epidemiologic Considerations, 26 Clinical Obstetrics & Gynecology 418, 424-25 (June 1983). Limb defects are even rarer, occurring in fewer than one birth out of every 1000. *Turpin*, 959 F.2d at 1353. But scientists simply do not know how teratogens (chemicals known to cause limb reduction defects) do their damage: They cannot reconstruct the biological chain of events that leads from an expectant mother's ingestion of a teratogenic substance to the stunted development of a baby's limbs. Nor do they know what it is about teratogens that causes them to have this effect. No doubt, someday we will have this

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[1] Limb reduction defects involve incomplete development of arms, legs, fingers and toes, such as the defects associated with the Thalidomide disaster of the 1960s.

knowledge, and then we will be able to tell precisely whether and how Bendectin (or any other suspected teratogen) interferes with limb development; in the current state of scientific knowledge, however, we are ignorant.

Not knowing the mechanism whereby a particular agent causes a particular effect is not always fatal to a plaintiff's claim. Causation can be proved even when we don't know precisely how the damage occurred, if there is sufficiently compelling proof that the agent must have caused the damage somehow. One method of proving causation in these circumstances is to use statistical evidence. If 50 people who eat at a restaurant one evening come down with food poisoning during the night, we can infer that the restaurant's food probably contained something unwholesome, even if none of the dishes is available for analysis. This inference is based on the fact that, in our health-conscious society, it is highly unlikely that 50 people who have nothing in common except that they ate at the same restaurant will get food poisoning from independent sources.

It is by such means that plaintiffs here seek to establish that Bendectin is responsible for their injuries. They rely on the testimony of three groups of scientific experts. One group proposes to testify that there is a statistical link between the ingestion of Bendectin during pregnancy and limb reduction defects. These experts have not themselves conducted epidemiological (human statistical) studies on the effects of Bendectin; rather, they have reanalyzed studies published by other scientists, none of whom reported a statistical association between Bendectin and birth defects. Other experts proffered by plaintiffs propose to testify that Bendectin causes limb reduction defects in humans because it causes such defects in laboratory animals. A third group of experts sees a link between Bendectin and birth defects because Bendectin has a chemical structure that is similar to other drugs suspected of causing birth defects.

The opinions proffered by plaintiffs' experts do not, to understate the point, reflect the consensus within the scientific community. The FDA - an agency not known for its promiscuity in approving drugs - continues to approve Bendectin for use by pregnant women because "available data do not demonstrate an

association between birth defects and Bendectin." U.S. Department of Health and Human Services News, No. P80-45 (Oct. 7, 1980). Every published study here and abroad - and there have been many - concludes that Bendectin is not a teratogen. Turpin, 959 F.2d at 1353-56. In fact, apart from the small but determined group of scientists testifying on behalf of the Bendectin plaintiffs in this and many other cases, there doesn't appear to be a single scientist who has concluded that Bendectin causes limb reduction defects.

It is largely because the opinions proffered by plaintiffs' experts run counter to the substantial consensus in the scientific community that we affirmed the district court's grant of summary judgment the last time the case appeared before us. *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 951 F.2d 1128, 1131 (9th Cir. 1992). The standard for admissibility of expert testimony in this circuit at the time was the so-called Frye test: Scientific evidence was admissible if it was based on a scientific technique generally accepted as reliable within the scientific community. *Frye v. United States*, 293 F. 1013, 1014 (D.C. Cir. 1923).[2] We found that the district court properly applied this standard, and affirmed. The Supreme Court reversed, holding that Frye was superceded by Federal Rule of Evidence 702, 113 S. Ct. at 2794, and remanded for us to consider the admissibility of plaintiffs' expert testimony under this new standard.

B. Procedural Issues

First, however, we address plaintiffs' argument that we should simply remand the case so the district court can make the initial determination of admissibility under the new standard announced by the Supreme Court. There is certainly something to be said for this position, as the district court is charged with making the initial determination whether to admit evidence. In the peculiar circumstances of this case, however, we have determined that the interests of justice and judicial economy will

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[2] We had adopted Frye as the law of the circuit in *United States v. Solomon*, 753 F.2d 1522, 1526 (9th Cir. 1985).

best be served by deciding those issues that are properly before us and, in the process, offering guidance on the application of the *Daubert* standard in this circuit.

The district court already made a determination as to admissibility, albeit under a different standard than we apply on remand, and granted summary judgment based on its exclusion of plaintiffs' expert testimony. *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 727 F. Supp. 570, 575-76 (S.D. Cal. 1989). A grant of summary judgment may be sustained on any basis supported by the record, *Leonard v. Clark*, 12 F.3d 885, 889 (9th Cir. 1993), so we shall consider whether the district court's grant of summary judgment can be sustained under the new standard announced by the Supreme Court. Our review here is, of course, very narrow: We will affirm the summary judgment only if, as a matter of law, the proffered evidence would have to be excluded at trial. The district court's power is far broader; were we to conclude that the expert testimony is not per se inadmissible, the district court on remand would nevertheless have discretion to reject it under Rule 403 or 702. *Daubert*, 113 S. Ct. at 2798. Such a ruling would be reviewed under the deferential abuse of discretion standard.

One other procedural matter detains us. According to plaintiffs, they weren't required to come forward with any evidence to survive summary judgment because the affidavit of Merrell's expert was itself inadmissible under *Daubert*; the burden thus never shifted to plaintiffs to demonstrate a genuine issue as to causation. Plaintiffs not only fail to mention the many other exhibits offered by Merrell, they also misunderstand the moving party's burden on summary judgment. Because plaintiffs bear the ultimate burden of proof on causation, Merrell had only to point to the absence of a genuine issue of material fact; it wasn't required to produce any evidence at all. *See Maffei v. Northern Insulation of New York*, 12 F.3d 892, 899 (9th Cir. 1993). Thus, the admissibility of Merrell's expert's affidavit is beside the point; the question is whether plaintiffs adduced enough admissible evidence to create a genuine issue of material fact as to whether Bendectin caused their injuries. *See Elkins v. Richardson-Merrell, Inc.*, 8 F.3d 1068, 1071-72 (6th Cir. 1993).

It is to that question we now turn.

II

A. Brave New World

Federal judges ruling on the admissibility of expert scientific testimony face a far more complex and daunting task in a post-*Daubert* world than before. The judge's task under *Frye* is relatively simple: to determine whether the method employed by the experts is generally accepted in the scientific community. *Solomon*, 753 F.2d at 1526. Under *Daubert*, we must engage in a difficult, two-part analysis. First, we must determine nothing less than whether the experts' testimony reflects "scientific knowledge," whether their findings are "derived by the scientific method," and whether their work product amounts to "good science." 113 S. Ct. at 2795, 2797. Second, we must ensure that the proposed expert testimony is "relevant to the task at hand," id. at 2797, i.e., that it logically advances a material aspect of the proposing party's case. The Supreme Court referred to this second prong of the analysis as the "fit" requirement. *Id.* at 2796.

The first prong of *Daubert* puts federal judges in an uncomfortable position. The question of admissibility only arises if it is first established that the individuals whose testimony is being proffered are experts in a particular scientific field; here, for example, the Supreme Court waxed eloquent on the impressive qualifications of plaintiffs' experts. *Id.* at 2791 n.2. Yet something doesn't become "scientific knowledge" just because it's uttered by a scientist; nor can an expert's self-serving assertion that his conclusions were "derived by the scientific method" be deemed conclusive, else the Supreme Court's opinion could have ended with footnote two. As we read the Supreme Court's teaching in *Daubert*, therefore, though we are largely untrained in science and certainly no match for any of the witnesses whose testimony we are reviewing, it is our responsibility to determine whether those experts' proposed testimony amounts to "scientific knowledge," constitutes "good science,"

and was "derived by the scientific method."

The task before us is more daunting still when the dispute concerns matters at the very cutting edge of scientific research, where fact meets theory and certainty dissolves into probability. As the record in this case illustrates, scientists often have vigorous and sincere disagreements as to what research methodology is proper, what should be accepted as sufficient proof for the existence of a "fact," and whether information derived by a particular method can tell us anything useful about the subject under study.

Our responsibility, then, unless we badly misread the Supreme Court's opinion, is to resolve disputes among respected, well-credentialed scientists about matters squarely within their expertise, in areas where there is no scientific consensus as to what is and what is not "good science," and occasionally to reject such expert testimony because it was not "derived by the scientific method." Mindful of our position in the hierarchy of the federal judiciary, we take a deep breath and proceed with this heady task.

B. Deus ex Machina

The Supreme Court's opinion in *Daubert* focuses closely on the language of Fed. R. Evid. 702, which permits opinion testimony by experts as to matters amounting to "scientific . . . knowledge." The Court recognized, however, that knowledge in this context does not mean absolute certainty. 113 S. Ct. at 2795. Rather, the Court said, "in order to qualify as 'scientific knowledge,' an inference or assertion must be derived by the scientific method." *Id.* Elsewhere in its opinion, the Court noted that Rule 702 is satisfied where the proffered testimony is "based on scientifically valid principles." *Id.* at 2799. Our task, then, is to analyze not what the experts say, but what basis they have for saying it.

Which raises the question: How do we figure out whether scientists have derived their findings through the scientific method or whether their testimony is based on scientifically valid principles? Each expert proffered by the plaintiffs assures us that he has "utilized the type of data that is generally and reasonably

relied upon by scientists" in the relevant field, *see, e.g.*, Newman Aff. at 5, and that he has "utilized the methods and methodology that would generally and reasonably be accepted" by people who deal in these matters, *see, e.g.*, Gross Aff. at 5. The Court held, however, that federal judges perform a "gate-keeping role," *Daubert*, 113 S. Ct. at 2798; to do so they must satisfy themselves that scientific evidence meets a certain standard of reliability before it is admitted. This means that the expert's bald assurance of validity is not enough. Rather, the party presenting the expert must show that the expert's findings are based on sound science, and this will require some objective, independent validation of the expert's methodology.

While declining to set forth a "definitive checklist or test," id. at 2796, the Court did list several factors federal judges can consider in determining whether to admit expert scientific testimony under Fed. R. Evid. 702: whether the theory or technique employed by the expert is generally accepted in the scientific community; whether it's been subjected to peer review and publication; whether it can be and has been tested; and whether the known or potential rate of error is acceptable. *Id.* at 2796-97.[3] We read these factors as illustrative rather than exhaustive; similarly, we do not deem each of them to be equally applicable (or applicable at all) in every case.[4] Rather, we read

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[3] These factors raise many questions, such as how do we determine whether the rate of error is acceptable, and by what standard? Or, what should we infer from the fact that the methodology has been tested, but only by the party's own expert or experts? Do we ask whether the methodology they employ to test their methodology is itself methodologically sound? Such questions only underscore the basic problem, which is that we must devise standards for acceptability where respected scientists disagree on what's acceptable.

[4] Two of the four factors mentioned by the Supreme Court would be difficult or impossible to apply to the expert testimony in this case. Only one of plaintiffs' experts has done original research. Dr. Crescitelli mentions that he "specifically performed studies" on Bendectin and its antihistamine component, Aff. at 3, but does not explain the nature of those studies or the methodology employed. The others have examined the available literature and studies within their respective fields and drawn

the Supreme Court as instructing us to determine whether the analysis undergirding the experts' testimony falls within the range of accepted standards governing how scientists conduct their research and reach their conclusions.

One very significant fact to be considered is whether the experts are proposing to testify about matters growing naturally and directly out of research they have conducted independent of the litigation, or whether they have developed their opinions expressly for purposes of testifying. That an expert testifies for money does not necessarily cast doubt on the reliability of his testimony, as few experts appear in court merely as an eleemosynary gesture. But in determining whether proposed expert testimony amounts to good science, we may not ignore the fact that a scientist's normal workplace is the lab or the field, not the courtroom or the lawyer's office.[5]

That an expert testifies based on research he has conducted independent of the litigation provides important, objective proof that the research comports with the dictates of good science. *See* Huber, GALILEO'S REVENGE at 206-09 (describing how the prevalent practice of expert-shopping leads to bad science). For one thing, experts whose findings flow from existing research are less likely to have been biased toward a particular conclusion by the promise of remuneration; when an expert prepares reports and findings before being hired as a witness, that record will

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different conclusions than the scientists who performed the original work. As to such derivative analytical work, it makes little sense to ask whether the technique employed "can be (and has been) tested," *Daubert*, 113 S. Ct. at 2796, or what its "known or potential rate of error" might be, *id.* at 2797.

[5] There are, of course, exceptions. Fingerprint analysis, voice recognition, DNA fingerprinting and a variety of other scientific endeavors closely tied to law enforcement may indeed have the courtroom as a principal theatre of operations. *See, e.g., United States v. Chischilly*, 30 F.3d 1144, 1153 (9th Cir. 1994) (admitting expert testimony concerning a DNA match as proof the defendant committed sexual abuse and murder). As to such disciplines, the fact that the expert has developed an expertise principally for purposes of litigation will obviously not be a substantial consideration.

limit the degree to which he can tailor his testimony to serve a party's interests. Then, too, independent research carries its own indicia of reliability, as it is conducted, so to speak, in the usual course of business and must normally satisfy a variety of standards to attract funding and institutional support. Finally, there is usually a limited number of scientists actively conducting research on the very subject that is germane to a particular case, which provides a natural constraint on parties' ability to shop for experts who will come to the desired conclusion. That the testimony proffered by an expert is based directly on legitimate, preexisting research unrelated to the litigation provides the most persuasive basis for concluding that the opinions he expresses were "derived by the scientific method."

We have examined carefully the affidavits proffered by plaintiffs' experts, as well as the testimony from prior trials that plaintiffs have introduced in support of that testimony, and find that none of the experts based his testimony on preexisting or independent research. While plaintiffs' scientists are all experts in their respective fields, none claims to have studied the effect of Bendectin on limb reduction defects before being hired to testify in this or related cases.

If the proffered expert testimony is not based on independent research, the party proffering it must come forward with other objective, verifiable evidence that the testimony is based on "scientifically valid principles." One means of showing this is by proof that the research and analysis supporting the proffered conclusions have been subjected to normal scientific scrutiny through peer review and publication.[6] *See* Peter W. Huber, GALILEO'S REVENGE: JUNK SCIENCE in the Courtroom 209 (1991) (suggesting that "the ultimate test of [a scientific expert's] integrity is her readiness to publish and be damned").

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[6] We refer, of course, to publication in a generally-recognized scientific journal that conditions publication on a bona fide process of peer review. *See Daubert*, 113 S. Ct. at 2797 ("The fact of publication (or lack thereof) in a peer-reviewed journal thus will be . . . relevant . . . .") (emphasis added). *See generally* The Journal's Peer-Review Process, 321 NEW ENG. J. MED. 837 (1989).

Peer review and publication do not, of course, guarantee that the conclusions reached are correct; much published scientific research is greeted with intense skepticism and is not borne out by further research. But the test under *Daubert* is not the correctness of the expert's conclusions but the soundness of his methodology. *See* n.11 *infra*. That the research is accepted for publication in a reputable scientific journal after being subjected to the usual rigors of peer review is a significant indication that it is taken seriously by other scientists, *i.e.*, that it meets at least the minimal criteria of good science. *Daubert*, 113 S. Ct. at 2797 ("scrutiny of the scientific community is a component of 'good science'"). If nothing else, peer review and publication "increase the likelihood that substantive flaws in methodology will be detected." *Daubert*, 113 S. Ct. at 2797.[7]

Bendectin litigation has been pending in the courts for over a decade, yet the only review the plaintiffs' experts' work has received has been by judges and juries, and the only place their theories and studies have been published is in the pages of federal and state reporters.[8] None of the plaintiffs' experts has published his work on Bendectin in a scientific journal or solicited formal review by his colleagues. Despite the many years the controversy has been brewing, no one in the scientific community - except defendant's experts - has deemed these studies worthy of verification, refutation or even comment. It's as if there were a tacit understanding within the scientific community that what's going on here is not science at all, but litigation.[9]

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[7] For instance, peer review might well have brought to light the more glaring arithmetical errors in the testimony presented by plaintiffs' experts in other Bendectin cases. *See DeLuca v. Merrell Dow Pharmaceuticals, Inc.*, 791 F. Supp. 1042, 1048 (D.N.J. 1992), *aff'd*, 6 F.3d 778, (3d Cir. 1993).

[8] As Judge Frank Johnson has succinctly noted, "the examination of a scientific study by a cadre of lawyers is not the same as its examination by others trained in the field of science or medicine." *Perry v. United States*, 755 F.2d 888, 892 (11th Cir. 1985).

[9] There may well be good reasons why a scientific study has not been

Establishing that an expert's proffered testimony grows out of pre-litigation research or that the expert's research has been subjected to peer review are the two principal ways the proponent of expert testimony can show that the evidence satisfies the first prong of Rule 702.[10] Where such evidence is unavailable, the proponent of expert scientific testimony may attempt to satisfy its burden through the testimony of its own experts. For such a showing to be sufficient, the experts must explain precisely how they went about reaching their conclusions and point to some objective source - a learned treatise, the policy statement of a professional association, a published article in a

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published. For example, it may be too recent or of insufficiently broad interest. *Daubert*, 113 S. Ct. at 2797. These reasons do not apply here. Except with respect to the views expressed in this litigation, plaintiffs' experts have been well-published, *see, e.g.*, Crescitelli Aff. at 3 (authored 125 formal papers, 80-100 short notes or abstracts, a half-dozen reviews, and articles concerning antihistamines and related compounds), and the opinions they proffer, if supported by sound methodology, would doubtless be greedily devoured by the machinery of peer review. A conclusion that Bendectin causes birth defects would be of significant public interest both in this country (where millions of women have taken Bendectin and the FDA continues to approve its use) and abroad (where Bendectin is still widely used). That plaintiffs' experts have been unable or unwilling to publish their work undermines plaintiffs' claim that the findings these experts proffer are "grounded in the methods and procedures of science" and "derived by the scientific method." *Daubert*, 113 S. Ct. at 2795, 2796.

[10] This showing would not, of course, be conclusive. Proffering scientific testimony and making an initial showing that it was derived by the scientific method enables a party to establish a prima facie case as to admissibility under Rule 702. The opposing party would then be entitled to challenge that showing. This it could do by presenting evidence (including expert testimony) that the proposing party's expert employed unsound methodology or failed to assiduously follow an otherwise sound protocol. Where the opposing party thus raises a material dispute as to the admissibility of expert scientific evidence, the district court must hold an in limine hearing (a so-called *Daubert* hearing) to consider the conflicting evidence and make findings about the soundness and reliability of the methodology employed by the scientific experts. *See* Fed. R. Evid. 104(a) ("In making its determination [the court] is not bound by the rules of evidence."); Fed. R. Evid. 706 (on the use of court-appointed experts).

reputable scientific journal or the like - to show that they have followed the scientific method, as it is practiced by (at least) a recognized minority of scientists in their field. *See United States v. Rincon*, 28 F.3d 921, 924 (9th Cir. 1994) (research must be described "in sufficient detail that the district court [can] determine if the research was scientifically valid").[11]

Plaintiffs have made no such showing. As noted above, plaintiffs rely entirely on the experts' unadorned assertions that the methodology they employed comports with standard scientific procedures. In support of these assertions, plaintiffs offer only the trial and deposition testimony of these experts in other cases. While these materials indicate that plaintiffs' experts have relied on animal studies, chemical structure analyses and epidemiological data, they neither explain the methodology the experts followed to reach their conclusions nor point to any external source to validate that methodology. We've been presented with only the experts' qualifications, their conclusions and their assurances of reliability. Under *Daubert*, that's not enough.

This is especially true of Dr. Palmer - the only expert willing to testify "that Bendectin did cause the limb defects in each of the children." Palmer Aff. at 8. In support of this conclusion, Dr. Palmer asserts only that Bendectin is a teratogen and that he has examined the plaintiffs' medical records, which apparently reveal the timing of their mothers' ingestion of the drug. Dr. Palmer offers no tested or testable theory to explain how, from this limited information, he was able to eliminate all

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[11] This underscores the difference between *Daubert* and *Frye*. Under *Frye*, the party proffering scientific evidence had to show it was based on the method generally accepted in the scientific community. The focus under *Daubert* is on the reliability of the methodology, and in addressing that question the court and the parties are not limited to what is generally accepted; methods accepted by a minority in the scientific community may well be sufficient. However, the party proffering the evidence must explain the expert's methodology and demonstrate in some objectively verifiable way that the expert has both chosen a reliable scientific method and followed it faithfully. Of course, the fact that one party's experts use a methodology accepted by only a minority of scientists would be a proper basis for impeachment at trial.

other potential causes of birth defects, nor does he explain how he alone can state as a fact that Bendectin caused plaintiffs' injuries. We therefore agree with the Sixth Circuit's observation that "Dr. Palmer does not testify on the basis of the collective view of his scientific discipline, nor does he take issue with his peers and explain the grounds for his differences. Indeed, no understandable scientific basis is stated. Personal opinion, not science, is testifying here." *Turpin*, 959 F.2d at 1360. For this reason, Dr. Palmer's testimony is inadmissible as a matter of law under Rule 702.

The failure to make any objective showing as to admissibility under the first prong of Rule 702 would also fatally undermine the testimony of plaintiffs' other experts, but for the peculiar posture of this case. Plaintiffs submitted their experts' affidavits while Frye was the law of the circuit and, although they've not requested an opportunity to augment their experts' affidavits in light of *Daubert*, the interests of justice would be disserved by precluding plaintiffs from doing so. Given the opportunity to augment their original showing of admissibility, plaintiffs might be able to show that the methodology adopted by some of their experts is based on sound scientific principles. For instance, plaintiffs' epidemiologists might validate their reanalyses by explaining why they chose only certain of the data that was available, or the experts relying on animal studies might point to some authority for extrapolating human causation from teratogenicity in animals.[12]

Were this the only question before us, we would be inclined to remand to give plaintiffs an opportunity to submit additional proof that the scientific testimony they proffer was "derived by the scientific method." *Daubert*, however, establishes two prongs to the Rule 702 admissibility inquiry. *See* pp. 71-72 *supra*. We

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[12] Dr. Palmer could not similarly bolster his testimony. Unlike the other experts, who speak in terms of probabilities, Dr. Palmer goes so far as to conclude that plaintiffs' injuries were in fact caused by Bendectin rather than another cause. The record in this case categorically refutes the notion that anyone can tell what caused the birth defects in any given case. *See* p. 68 *supra*.

therefore consider whether the testimony satisfies the second prong of Rule 702: Would plaintiffs' proffered scientific evidence "assist the trier of fact to . . . determine a fact in issue"? Fed. R. Evid. 702.

C. No Visible Means of Support

In elucidating the second requirement of Rule 702, *Daubert* stressed the importance of the "fit" between the testimony and an issue in the case: "Rule 702's 'helpfulness' standard requires a valid scientific connection to the pertinent inquiry as a precondition to admissibility." 113 S. Ct. at 2796. Here, the pertinent inquiry is causation. In assessing whether the proffered expert testimony "will assist the trier of fact" in resolving this issue, we must look to the governing substantive standard, which in this case is supplied by California tort law.

Plaintiffs do not attempt to show causation directly; instead, they rely on experts who present circumstantial proof of causation. Plaintiffs' experts testify that Bendectin is a teratogen because it causes birth defects when it is tested on animals, because it is similar in chemical structure to other suspected teratogens, and because statistical studies show that Bendectin use increases the risk of birth defects. Modern tort law permits such proof, but plaintiffs must nevertheless carry their traditional burden; they must prove that their injuries were the result of the accused cause and not some independent factor. In the case of birth defects, carrying this burden is made more difficult because we know that some defects - including limb reduction defects - occur even when expectant mothers do not take Bendectin, and that most birth defects occur for no known reason.

California tort law requires plaintiffs to show not merely that Bendectin increased the likelihood of injury, but that it more likely than not caused their injuries. *See Jones v. Ortho Pharmaceutical Corp.*, 163 Cal. App. 3d 396, 403, 209 Cal. Rptr. 456 (Cal. Ct. App. 1985). In terms of statistical proof, this means that plaintiffs must establish not just that their mothers' ingestion of Bendectin increased somewhat the likelihood of birth defects, but that it more than doubled it - only then can it be said that

Bendectin is more likely than not the source of their injury. Because the background rate of limb reduction defects is one per thousand births, plaintiffs must show that among children of mothers who took Bendectin the incidence of such defects was more than two per thousand.[13]

None of plaintiffs' epidemiological experts claims that ingestion of Bendectin during pregnancy more than doubles the risk of birth defects.[14] To evaluate the relationship between Bendectin and limb reduction defects, an epidemiologist would take a sample of the population and compare the frequency of birth defects in children whose mothers took Bendectin with the frequency of defects in children whose mothers did not. *See DeLuca*, 911 F.2d 941 at 946. The ratio derived from this comparison would be an estimate of the "relative risk" associated with Bendectin. *See generally* Joseph L. Fleiss, Statistical Methods for Rates and Proportions (2d ed. 1981). For an epidemiological study to show causation under a preponderance standard, "the relative risk of limb reduction defects arising from the epidemiological data . . . will, at a minimum, have to exceed

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[13] No doubt, there will be unjust results under this substantive standard. If a drug increases the likelihood of birth defects, but doesn't more than double it, some plaintiffs whose injuries are attributable to the drug will be unable to recover. There is a converse unfairness under a regime that allows recovery to everyone that may have been affected by the drug. Under this regime, all potential plaintiffs are entitled to recover, even though most will not have suffered an injury that can be attributed to the drug. One can conclude from this that unfairness is inevitable when our tools for detecting causation are imperfect and we must rely on probabilities rather than more direct proof. In any event, this is a matter to be sorted out by the states, whose substantive legal standards we are bound to apply. *See O'Melveny & Myers v. FDIC*, 129 L. Ed. 2d 67, 114 S. Ct. 2048, 2053 (1994).

[14] The only exception is Dr. Done, who in another case presented metaanalysis studies purporting to show a relative risk greater than two. But his conclusion in that case rested on a demonstrably faulty methodology, *see DeLuca*, 791 F. Supp. at 1047-59, and perhaps for that reason was not proffered here.

'2'." *DeLuca*, 911 F.2d at 958.[15] That is, the study must show that children whose mothers took Bendectin are more than twice as likely to develop limb reduction birth defects as children whose mothers did not.[16] While plaintiffs' epidemiologists make vague assertions that there is a statistically significant relationship between Bendectin and birth defects, none states that the relative risk is greater than two. These studies thus would not be helpful, and indeed would only serve to confuse the jury, if offered to prove rather than refute causation. A relative risk of less than two may suggest teratogenicity, but it actually tends to disprove legal causation as it shows that Bendectin does not double the likelihood of birth defects.[17]

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[15] For a more complete explanation of the relationship between the burden of proof and relative risk, *see* Robert P. Charrow & David E. Bernstein, *Scientific Evidence in the Courtroom: Admissibility and Statistical Significance after* Daubert 28-33 (Wash. Legal Found., 1994).

[16] A statistical study showing a relative risk of less than two could be combined with other evidence to show it is more likely than not that the accused cause is responsible for a particular plaintiff's injury. For example, a statistical study may show that a particular type of birth defect is associated with some unknown causes, as well as two known potential causes - *e.g.*, smoking and drinking. If a study shows that the relative risk of injury for those who smoke is 1.5 as compared to the general population, while it is 1.8 for those who drink, a plaintiff who does not drink might be able to reanalyze the data to show that the study of smoking did not account for the effect of drinking on the incidence of birth defects in the general population. By making the appropriate comparison - between non-drinkers who smoke and non-drinkers who do not smoke - the teetotaller plaintiff might be able to show that the relative risk of smoking for her is greater than two. Here, however, plaintiffs' experts did not seek to differentiate these plaintiffs from the subjects of the statistical studies. The studies must therefore stand or fall on their own.

[17] The Supreme Court recognized that the "fit" requirement "goes primarily to relevance," *Daubert*, 113 S. Ct. at 2795, but it obviously did not intend the second prong of Rule 702 to be merely a reiteration of the general relevancy requirement of Rule 402. In elucidating the "fit" requirement, the Supreme Court noted that scientific expert testimony carries special dangers to the fact-finding process because it "'can be both powerful and quite misleading because of the difficulty in evaluating it.'"

With the exception of Dr. Palmer, whose testimony is inadmissible under the first prong of the Rule 702 analysis, see pp. 17-18 supra,[18] the remaining experts proffered by plaintiffs were equally unprepared to testify that Bendectin caused plaintiffs' injuries; they were willing to testify only that Bendectin is "capable of causing" birth defects. Crescitelli Aff. at 3, 8; Glasser Aff. at 6, 8; Gross Aff. at 9; Newman Aff. at 5, 9; Swan Aff. at 7. Plaintiffs argue "these scientists use the words 'capable of causing' meaning that it does cause. This is an ambiguity of language . . . . If something is capable of causing damage in humans, it does." Tape of Oral Arg. Mar. 22, 1994. But what plaintiffs must prove is not that Bendectin causes some birth defects, but that it caused their birth defects. To show this, plaintiffs' experts would have had to testify either that Bendectin actually caused plaintiffs' injuries (which they could not say) or that Bendectin more than doubled the likelihood of limb reduction birth defects (which they did not say).

As the district court properly found below, "the strongest inference to be drawn for plaintiffs based on the epidemiological evidence is that Bendectin could possibly have caused plaintiffs' injuries." 727 F. Supp. at 576. The same is true of the other testimony derived from animal studies and chemical structure analyses - these experts "testify to a possibility rather than a probability." *Turpin*, 959 F.2d at 1360. Plaintiffs do not quantify this possibility, or otherwise indicate how their conclusions about causation should be weighted, even though the substantive legal

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Id. at 2798 (quoting Weinstein, Rule 702 of the Federal Rules of Evidence Is Sound; It Should Not Be Amended, 138 F.R.D. 631, 632 (1991)). Federal judges must therefore exclude proffered scientific evidence under Rules 702 and 403 unless they are convinced that it speaks clearly and directly to an issue in dispute in the case, and that it will not mislead the jury.

[18] Dr. Palmer's testimony would easily meet Rule 702's fit requirement, were it not rendered inadmissible by the total lack of scientific basis for his conclusions. *See* pp. 17-19 & n.12 *supra*. Dr. Palmer's testimony thus illustrates how the two prongs of Rule 702 work in tandem to ensure that junk science is kept out of the federal courtroom.

standard has always required proof of causation by a preponderance of the evidence.[19] Unlike these experts' explanation of their methodology, this is not a shortcoming that could be corrected on remand; plaintiffs' experts could augment their affidavits with independent proof that their methods were sound, but to augment the substantive testimony as to causation would require the experts to change their conclusions altogether. Any such tailoring of the experts' conclusions would, at this stage of the proceedings, fatally undermine any attempt to show that these findings were "derived by the scientific method." Plaintiffs' experts must, therefore, stand by the conclusions they originally proffered, rendering their testimony inadmissible under the second prong of Fed. R. Evid. 702.

Conclusion

The district court's grant of summary judgment is AFFIRMED.

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[19] Several circuits have conducted a similar analysis in finding plaintiffs' expert testimony insufficient to prove causation as a matter of law. *See Elkins*, 8 F.3d at 1071-72; *Turpin*, 959 F.2d at 1359-61; *Ealy v. Richardson-Merrell, Inc.*, 283 U.S. App. D.C. 137, 897 F.2d 1159, 1163 (D.C. Cir. 1990); *Brock v. Merrell Dow Pharmaceuticals, Inc.*, 874 F.2d 307, 311-15 (5th Cir. 1989); *Lynch v. Merrell-Nat'l Labs.*, 830 F.2d 1190, 1195-97 (1st Cir. 1987).

APPENDIX B

UNITED STATES COURT OF APPEALS
For the Ninth Circuit

No. 90-55397

WILLIAM DAUBERT; JOYCE DAUBERT, individually and as Guardians Ad Litem for JASON DAUBERT, a minor; ANITA DE YOUNG, individually, and As Guardian Ad Litem for ERIC SCHULLER,

Plaintiffs-Appellants,

v.

MERRELL DOW PHARMACEUTICALS, INC., a Delaware corporation,

Defendant-Appellee.

ORDER

Filed May 3, 1995

Before: Alex Kozinski and O'Scannlain, Circuit Judges, and Stephen M. McNamee,* District Judge.

The panel has voted to deny appellants' petition for rehearing. The full court was advised of the suggestion for rehearing en banc. An active judge requested a vote on whether to rehear the matter en banc. The matter failed to receive a majority of the votes of the nonrecused active judges in favor of en banc consideration. Fed. R. App. P. 35.

The petition for rehearing is denied and the suggestion for rehearing en banc is rejected.

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* The Honorable Stephen M. McNamee, United States District Judge for the District of Arizona, sitting by designation.

APPENDIX C

SUPREME COURT OF THE UNITED STATES

WILLIAM DAUBERT, et ux., etc., et al.,

Petitioners,

v.

MERRELL DOW PHARMACEUTICALS, INC.,

Respondents.

No. 92-102

March 30, 1993, Argued
June 28, 1993, Decided

ON WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE NINTH CIRCUIT.

BLACKMUN, J., delivered the opinion for a unanimous Court with respect to Parts I and II-A, and the opinion of the Court with respect to Parts II-B, II-C, III, and IV, in which WHITE, O'CONNOR, SCALIA, KENNEDY, SOUTER, and THOMAS, JJ., joined. REHNQUIST, C. J., filed an opinion concurring in part and dissenting in part, in which STEVENS, J., joined.

In this case we are called upon to determine the standard for admitting expert scientific testimony in a federal trial.

I

Petitioners Jason Daubert and Eric Schuller are minor children born with serious birth defects. They and their parents

sued respondent in California state court, alleging that the birth defects had been caused by the mothers' ingestion of Bendectin, a prescription anti-nausea drug marketed by respondent. Respondent removed the suits to federal court on diversity grounds.

After extensive discovery, respondent moved for summary judgment, contending that Bendectin does not cause birth defects in humans and that petitioners would be unable to come forward with any admissible evidence that it does. In support of its motion, respondent submitted an affidavit of Steven H. Lamm, physician and epidemiologist, who is a well-credentialed expert on the risks from exposure to various chemical substances.[1] Doctor Lamm stated that he had reviewed all the literature on Bendectin and human birth defects — more than 30 published studies involving over 130,000 patients. No study had found Bendectin to be a human teratogen (*i.e.*, a substance capable of causing malformations in fetuses). On the basis of this review, Doctor Lamm concluded that maternal use of Bendectin during the first trimester of pregnancy has not been shown to be a risk factor for human birth defects.

Petitioners did not (and do not) contest this characterization of the published record regarding Bendectin. Instead, they responded to respondent's motion with the testimony of eight experts of their own, each of whom also possessed impressive credentials.[2] These experts had concluded that Bendectin can

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[1] Doctor Lamm received his master's and doctor of medicine degrees from the University of Southern California. He has served as a consultant in birth-defect epidemiology for the National Center for Health Statistics and has published numerous articles on the magnitude of risk from exposure to various chemical and biological substances. App. 34-44.

[2] For example, Shanna Helen Swan, who received a master's degree in biostatics from Columbia University and a doctorate in statistics from the University of California at Berkeley, is chief of the section of the California Department of Health and Services that determines causes of birth defects, and has served as a consultant to the World Health Organization, the Food and Drug Administration, and the National Institutes of Health. App. 113-114, 131-132. Stewart A. Newman, who received his master's and a doctorate in chemistry from Columbia University and the University of Chicago, respectively, is a professor at New York Medical

cause birth defects. Their conclusions were based upon "in vitro" (test tube) and "in vivo" (live) animal studies that found a link between Bendectin and malformations; pharmacological studies of the chemical structure of Bendectin that purported to show similarities between the structure of the drug and that of other substances known to cause birth defects; and the "reanalysis" of previously published epidemiological (human statistical) studies.

The District Court granted respondent's motion for summary judgment. The court stated that scientific evidence is admissible only if the principle upon which it is based is "'sufficiently established to have general acceptance in the field to which it belongs.'" 727 F. Supp. 570, 572 (SD Cal. 1989), quoting *United States v. Kilgus*, 571 F.2d 508, 510 (CA9 1978). The court concluded that petitioners' evidence did not meet this standard. Given the vast body of epidemiological data concerning Bendectin, the court held, expert opinion which is not based on epidemiological evidence is not admissible to establish causation. 727 F. Supp., at 575. Thus, the animal-cell studies, live-animal studies, and chemical-structure analyses on which petitioners had relied could not raise by themselves a reasonably disputable jury issue regarding causation. *Ibid.* Petitioners' epidemiological analyses, based as they were on recalculations of data in previously published studies that had found no causal link between the drug and birth defects, were ruled to be inadmissible because they had not been published or subjected to peer review. *Ibid.*

The United States Court of Appeals for the Ninth Circuit affirmed. 951 F.2d 1128 (1991). Citing *Frye v. United States*, 54 App. D.C. 46, 47, 293 F. 1013, 1014 (1923), the court stated that expert opinion based on a scientific technique is inadmissible unless the technique is "generally accepted" as reliable in the relevant scientific community. 951 F.2d, at 1129-1130. The court

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College and has spent over a decade studying the effect of chemicals on limb development. App. 54-56. The credentials of the others are similarly impressive. *See* App. 61-66, 73-80, 148-153, 187-192, and Attachment to Petitioners' Opposition to Summary Judgment, Tabs 12, 20, 21, 26, 31, 32.

declared that expert opinion based on a methodology that diverges "significantly from the procedures accepted by recognized authorities in the field . . . cannot be shown to be 'generally accepted as a reliable technique.'" *Id.*, at 1130, quoting *United States v. Solomon*, 753 F.2d 1522, 1526 (CA9 1985).

The court emphasized that other Courts of Appeals considering the risks of Bendectin had refused to admit reanalyses of epidemiological studies that had been neither published nor subjected to peer review. 951 F.2d, at 1130-1131. Those courts had found unpublished reanalyses "particularly problematic in light of the massive weight of the original published studies supporting [respondent's] position, all of which had undergone full scrutiny from the scientific community." *Id.*, at 1130. Contending that reanalysis is generally accepted by the scientific community only when it is subjected to verification and scrutiny by others in the field, the Court of Appeals rejected petitioners' reanalyses as "unpublished, not subjected to the normal peer review process and generated solely for use in litigation." *Id.*, at 1131. The court concluded that petitioners' evidence provided an insufficient foundation to allow admission of expert testimony that Bendectin caused their injuries and, accordingly, that petitioners could not satisfy their burden of proving causation at trial.

We granted certiorari, ___ U.S. ___ (1992), in light of sharp divisions among the courts regarding the proper standard for the admission of expert testimony. *Compare, e.g., United States v. Shorter*, 257 U.S. App. D.C. 358, 363-364, 809 F.2d 54, 59-60 (applying the "general acceptance" standard), *cert. denied*, 484 U.S. 817, 98 L. Ed. 2d 35, 108 S. Ct. 71 (1987), with *DeLuca v. Merrell Dow Pharmaceuticals, Inc.*, 911 F.2d 941, 955 (CA3 1990) (rejecting the "general acceptance" standard).

II

A

In the 70 years since its formulation in the *Frye* case, the "general acceptance" test has been the dominant standard for

determining the admissibility of novel scientific evidence at trial. *See* E. Green & C. Nesson, Problems, Cases, and Materials on Evidence 649 (1983). Although under increasing attack of late, the rule continues to be followed by a majority of courts, including the Ninth Circuit.[3]

The *Frye* test has its origin in a short and citation-free 1923 decision concerning the admissibility of evidence derived from a systolic blood pressure deception test, a crude precursor to the polygraph machine. In what has become a famous (perhaps infamous) passage, the then Court of Appeals for the District of Columbia described the device and its operation and declared: "Just when a scientific principle or discovery crosses the line between the experimental and demonstrable stages is difficult to define. Somewhere in this twilight zone the evidential force of the principle must be recognized, and while courts will go a long way in admitting expert testimony deduced from a well-recognized scientific principle or discovery, the thing from which the deduction is made must be sufficiently established to have gained general acceptance in the particular field in which it belongs." 54 App. D.C., at 47, 293 F., at 1014 (emphasis added).

Because the deception test had "not yet gained such standing and scientific recognition among physiological and psychological authorities as would justify the courts in admitting expert testimony deduced from the discovery, development, and experiments thus far made," evidence of its results was ruled inadmissible. *Ibid.*

The merits of the *Frye* test have been much debated, and scholarship on its proper scope and application is legion.[4]

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[3] For a catalogue of the many cases on either side of this controversy, *see* P. Gianelli & E. Imwinkelried, Scientific Evidence § 1-5, pp. 10-14 (1986 & Supp. 1991).

[4] *See, e.g.*, Green, Expert Witnesses and Sufficiency of Evidence in Toxic Substances Litigation: The Legacy of Agent Orange and Bendectin Litigation, 86 Nw. U. L. Rev. 643 (1992) (hereinafter Green); Becker & Orenstein, The Federal Rules of Evidence After Sixteen Years -- The Effect of "Plain Meaning" Jurisprudence, the Need for an Advisory Committee on the Rules of Evidence, and Suggestions for Selective

Petitioners' primary attack, however, is not on the content but on the continuing authority of the rule. They contend that the *Frye* test was superseded by the adoption of the Federal Rules of Evidence.[5] We agree.

We interpret the legislatively-enacted Federal Rules of Evidence as we would any statute. *Beech Aircraft Corp. v. Rainey*, 488 U.S. 153, 163, 102 L. Ed. 2d 445, 109 S. Ct. 439 (1988). Rule 402 provides the baseline: "All relevant evidence is admissible, except as otherwise provided by the Constitution of the United States, by Act of Congress, by these rules, or by other rules prescribed by the Supreme Court pursuant to statutory authority. Evidence which is not relevant is not admissible."

Revision of the Rules, 60 Geo. Wash.L.Rev. 857, 876-885 (1992); Hanson, "James Alphonso Frye is Sixty-Five Years Old; Should He Retire?," 16 W. St. U. L. Rev. 357 (1989); Black, A Unified Theory of Scientific Evidence, 56 Ford. L. Rev. 595 (1988); Imwinkelried, The "Bases" of Expert Testimony: The Syllogistic Structure of Scientific Testimony, 67 N.C. L. Rev. 1 (1988); Proposals for a Model Rule on the Admissibility of Scientific Evidence, 26 Jurimetrics J. 235 (1986); Gianelli, The Admissibility of Novel Scientific Evidence: *Frye v. United States*, A Half-Century Later, 80 Colum. L. Rev. 1197 (1980); The Supreme Court, 1986 Term, 101 Harv. L. Rev. 7, 119, 125-127 (1987).

Indeed, the debates over Frye are such a well-established part of the academic landscape that a distinct term -- "*Frye*-ologist" -- has been advanced to describe those who take part. *See* Behringer, Introduction, Proposals for a Model Rule on the Admissibility of Scientific Evidence, 26 Jurimetrics J., at 239, quoting Lacey, Scientific Evidence, 24 Jurimetrics J. 254, 264 (1984).

[5] Like the question of *Frye*'s merit, the dispute over its survival has divided courts and commentators. *Compare, e.g., United States v. Williams*, 583 F.2d 1194 (CA2 1978), *cert. denied*, 439 U.S. 1117, 59 L. Ed. 2d 77, 99 S. Ct. 1025 (1979) (*Frye* is superseded by the Rules of Evidence), with *Christophersen v. Allied-Signal Corp.*, 939 F.2d 1106, 1111, 1115-1116 (CA5 1991) (en banc) (*Frye* and the Rules coexist), *cert. denied*, ___ U.S. ___ (1992), 3 J. Weinstein & M. Berger, Weinstein's Evidence P 702[03], pp. 702-36 to 702-37 (1988) (hereinafter Weinstein & Berger) (*Frye* is dead), and M. Graham, Handbook of Federal Evidence § 703.2 (2d ed. 1991) (*Frye* lives). *See generally* P. Gianelli & E. Imwinkelried, Scientific Evidence § 1-5, pp. 28-29 (1986 & Supp. 1991) (citing authorities).

"Relevant evidence" is defined as that which has "any tendency to make the existence of any fact that is of consequence to the determination of the action more probable or less probable than it would be without the evidence." Rule 401. The Rule's basic standard of relevance thus is a liberal one.

Frye, of course, predated the Rules by half a century. In *United States v. Abel*, 469 U.S. 45, 83 L. Ed. 2d 450, 105 S. Ct. 465 (1984), we considered the pertinence of background common law in interpreting the Rules of Evidence. We noted that the Rules occupy the field, *id.*, at 49, but, quoting Professor Cleary, the Reporter, explained that the common law nevertheless could serve as an aid to their application: "In principle, under the Federal Rules no common law of evidence remains. 'All relevant evidence is admissible, except as otherwise provided . . . .' In reality, of course, the body of common law knowledge continues to exist, though in the somewhat altered form of a source of guidance in the exercise of delegated powers." *Id.*, at 51-52.

We found the common-law precept at issue in the Abel case entirely consistent with Rule 402's general requirement of admissibility, and considered it unlikely that the drafters had intended to change the rule. Id., at 50-51. In *Bourjaily v. United States*, 483 U.S. 171, 97 L. Ed. 2d 144, 107 S. Ct. 2775 (1987), on the other hand, the Court was unable to find a particular common-law doctrine in the Rules, and so held it superseded.

Here there is a specific Rule that speaks to the contested issue. Rule 702, governing expert testimony, provides: "If scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training, or education, may testify thereto in the form of an opinion or otherwise."

Nothing in the text of this Rule establishes "general acceptance" as an absolute prerequisite to admissibility. Nor does respondent present any clear indication that Rule 702 or the Rules as a whole were intended to incorporate a "general acceptance" standard. The drafting history makes no mention of *Frye*, and a rigid "general acceptance" requirement would be at

odds with the "liberal thrust" of the Federal Rules and their "general approach of relaxing the traditional barriers to 'opinion' testimony." *Beech Aircraft Corp. v. Rainey*, 488 U.S., at 169 (citing Rules 701 to 705). *See also* Weinstein, Rule 702 of the Federal Rules of Evidence is Sound; It Should Not Be Amended, 138 F.R.D. 631, 631 (1991) ("The Rules were designed to depend primarily upon lawyer-adversaries and sensible triers of fact to evaluate conflicts"). Given the Rules' permissive backdrop and their inclusion of a specific rule on expert testimony that does not mention "general acceptance," the assertion that the Rules somehow assimilated *Frye* is unconvincing. *Frye* made 'general acceptance' the exclusive test for admitting expert scientific testimony. That austere standard, absent from and incompatible with the Federal Rules of Evidence, should not be applied in federal trials.[6]

B

That the *Frye* test was displaced by the Rules of Evidence does not mean, however, that the Rules themselves place no limits on the admissibility of purportedly scientific evidence.[7] Nor is the trial judge disabled from screening such evidence. To the contrary, under the Rules the trial judge must ensure that any and all scientific testimony or evidence admitted is not only relevant, but reliable.

The primary locus of this obligation is Rule 702, which clearly contemplates some degree of regulation of the subjects

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[6] Because we hold that Frye has been superseded and base the discussion that follows on the content of the congressionally-enacted Federal Rules of Evidence, we do not address petitioners' argument that application of the *Frye* rule in this diversity case, as the application of a judge-made rule affecting substantive rights, would violate the doctrine of *Erie R. Co. v. Tompkins*, 304 U.S. 64, 82 L. Ed. 1188, 58 S. Ct. 817 (1938).

[7] THE CHIEF JUSTICE "does not doubt that Rule 702 confides to the judge some gatekeeping responsibility," post, at 4, but would neither say how it does so, nor explain what that role entails. We believe the better course is to note the nature and source of the duty.

and theories about which an expert may testify. "If scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue" an expert "may testify thereto." The subject of an expert's testimony must be "scientific . . . knowledge."[8] The adjective "scientific" implies a grounding in the methods and procedures of science. Similarly, the word "knowledge" connotes more than subjective belief or unsupported speculation. The term "applies to any body of known facts or to any body of ideas inferred from such facts or accepted as truths on good grounds." Webster's Third New International Dictionary 1252 (1986). Of course, it would be unreasonable to conclude that the subject of scientific testimony must be "known" to a certainty; arguably, there are no certainties in science. See, e. g., Brief for Nicolaas Bloembergen et al. as Amici Curiae 9 ("Indeed, scientists do not assert that they know what is immutably 'true' — they are committed to searching for new, temporary theories to explain, as best they can, phenomena"); Brief for American Association for the Advancement of Science and the National Academy of Sciences as Amici Curiae 7-8 ("Science is not an encyclopedic body of knowledge about the universe. Instead, it represents a process for proposing and refining theoretical explanations about the world that are subject to further testing and refinement") (emphasis in original). But, in order to qualify as "scientific knowledge," an inference or assertion must be derived by the scientific method. Proposed testimony must be supported by appropriate validation — i.e., "good grounds," based on what is known. In short, the requirement that an expert's testimony pertain to "scientific knowledge" establishes a standard of evidentiary reliability.[9]

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[8] Rule 702 also applies to "technical, or other specialized knowledge." Our discussion is limited to the scientific context because that is the nature of the expertise offered here.

[9] We note that scientists typically distinguish between "validity" (does the principle support what it purports to show?) and "reliability" (does application of the principle produce consistent results?). *See* Black, A Unified Theory of Scientific Evidence, 56 Ford. L. Rev. 595, 599 (1988). Although "the difference between accuracy, validity, and reliability may

Rule 702 further requires that the evidence or testimony "assist the trier of fact to understand the evidence or to determine a fact in issue." This condition goes primarily to relevance. "Expert testimony which does not relate to any issue in the case is not relevant and, ergo, non-helpful." 3 Weinstein & Berger P 702[02], p. 702-18. *See also United States v. Downing*, 753 F.2d 1224, 1242 (CA3 1985) ("An additional consideration under Rule 702 — and another aspect of relevancy — is whether expert testimony proffered in the case is sufficiently tied to the facts of the case that it will aid the jury in resolving a factual dispute"). The consideration has been aptly described by Judge Becker as one of "fit." *Ibid.* "Fit" is not always obvious, and scientific validity for one purpose is not necessarily scientific validity for other, unrelated purposes. *See Starrs, Frye v. United States* Restructured and Revitalized: A Proposal to Amend Federal Evidence Rule 702, and 26 Jurimetrics J. 249, 258 (1986). The study of the phases of the moon, for example, may provide valid scientific "knowledge" about whether a certain night was dark, and if darkness is a fact in issue, the knowledge will assist the trier of fact. However (absent creditable grounds supporting such a link), evidence that the moon was full on a certain night will not assist the trier of fact in determining whether an individual was unusually likely to have behaved irrationally on that night. Rule 702's "helpfulness" standard requires a valid scientific

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be such that each is distinct from the other by no more than a hen's kick," Starrs, *Frye v. United States* Restructured and Revitalized: A Proposal to Amend Federal Evidence Rule 702, 26 Jurimetrics J. 249, 256 (1986), our reference here is to evidentiary reliability -- that is, trustworthiness. *Cf.*, *e.g.*, Advisory Committee's Notes on Fed. Rule Evid. 602 ("'The rule requiring that a witness who testifies to a fact which can be perceived by the senses must have had an opportunity to observe, and must have actually observed the fact' is a 'most pervasive manifestation' of the common law insistence upon 'the most reliable sources of information.'" (citation omitted)); Advisory Committee's Notes on Art. VIII of the Rules of Evidence (hearsay exceptions will be recognized only "under circumstances supposed to furnish guarantees of trustworthiness"). In a case involving scientific evidence, evidentiary reliability will be based upon scientific validity.

connection to the pertinent inquiry as a precondition to admissibility.

That these requirements are embodied in Rule 702 is not surprising. Unlike an ordinary witness, see Rule 701, an expert is permitted wide latitude to offer opinions, including those that are not based on first-hand knowledge or observation. *See* Rules 702 and 703. Presumably, this relaxation of the usual requirement of first-hand knowledge — a rule which represents "a 'most pervasive manifestation' of the common law insistence upon 'the most reliable sources of information,'" Advisory Committee's Notes on Fed. Rule Evid. 602 (citation omitted) — is premised on an assumption that the expert's opinion will have a reliable basis in the knowledge and experience of his discipline.

C

Faced with a proffer of expert scientific testimony, then, the trial judge must determine at the outset, pursuant to Rule 104(a),[10] whether the expert is proposing to testify to **(1)** scientific knowledge that **(2)** will assist the trier of fact to understand or determine a fact in issue.[11] This entails a preliminary assessment of whether the reasoning or methodology

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[10] Rule 104(a) provides:

"Preliminary questions concerning the qualification of a person to be a witness, the existence of a privilege, or the admissibility of evidence shall be determined by the court, subject to the provisions of subdivision (b) [pertaining to conditional admissions]. In making its determination it is not bound by the rules of evidence except those with respect to privileges." These matters should be established by a preponderance of proof. *See Bourjaily v. United States*, 483 U.S. 171, 175-176, 97 L. Ed. 2d 144, 107 S. Ct. 2775 (1987).

[11] Although the *Frye* decision itself focused exclusively on "novel" scientific techniques, we do not read the requirements of Rule 702 to apply specially or exclusively to unconventional evidence. Of course, well-established propositions are less likely to be challenged than those that are novel, and they are more handily defended. Indeed, theories that are so firmly established as to have attained the status of scientific law, such as the laws of thermodynamics, properly are subject to judicial notice under Fed. Rule Evid. 201.

underlying the testimony is scientifically valid and of whether that reasoning or methodology properly can be applied to the facts in issue. We are confident that federal judges possess the capacity to undertake this review. Many factors will bear on the inquiry, and we do not presume to set out a definitive checklist or test. But some general observations are appropriate.

Ordinarily, a key question to be answered in determining whether a theory or technique is scientific knowledge that will assist the trier of fact will be whether it can be (and has been) tested. "Scientific methodology today is based on generating hypotheses and testing them to see if they can be falsified; indeed, this methodology is what distinguishes science from other fields of human inquiry." *Green*, at 645. *See also* C. Hempel, Philosophy of Natural Science 49 (1966) ("The statements constituting a scientific explanation must be capable of empirical test"); K. Popper, Conjectures and Refutations: The Growth of Scientific Knowledge 37 (5th ed. 1989) ("The criterion of the scientific status of a theory is its falsifiability, or refutability, or testability").

Another pertinent consideration is whether the theory or technique has been subjected to peer review and publication. Publication (which is but one element of peer review) is not a sine qua non of admissibility; it does not necessarily correlate with reliability, *see* S. Jasanoff, The Fifth Branch: Science Advisors as Policymakers 61-76 (1990), and in some instances well-grounded but innovative theories will not have been published, *see* Horrobin, The Philosophical Basis of Peer Review and the Suppression of Innovation, 263 J. Am. Med. Assn. 1438 (1990). Some propositions, moreover, are too particular, too new, or of too limited interest to be published. But submission to the scrutiny of the scientific community is a component of "good science," in part because it increases the likelihood that substantive flaws in methodology will be detected. *See* J. Ziman, Reliable Knowledge: An Exploration of the Grounds for Belief in Science 130-133 (1978); Relman and Angell, How Good Is Peer Review?, 321 New Eng. J. Med. 827 (1989). The fact of publication (or lack thereof) in a peer-reviewed journal thus will be a relevant, though not dispositive, consideration in assessing

the scientific validity of a particular technique or methodology on which an opinion is premised.

Additionally, in the case of a particular scientific technique, the court ordinarily should consider the known or potential rate of error, *see, e.g., United States v. Smith*, 869 F.2d 348, 353-354 (CA7 1989) (surveying studies of the error rate of spectrographic voice identification technique), and the existence and maintenance of standards controlling the technique's operation. *See United States v. Williams*, 583 F.2d 1194, 1198 (CA2 1978) (noting professional organization's standard governing spectrographic analysis), *cert. denied*, 439 U.S. 1117, 59 L. Ed. 2d 77, 99 S. Ct. 1025 (1979).

Finally, "general acceptance" can yet have a bearing on the inquiry. A "reliability assessment does not require, although it does permit, explicit identification of a relevant scientific community and an express determination of a particular degree of acceptance within that community." *United States v. Downing*, 753 F.2d, at 1238. *See also* 3 Weinstein & Berger P 702[03], pp. 702-41 to 702-42. Widespread acceptance can be an important factor in ruling particular evidence admissible, and "a known technique that has been able to attract only minimal support within the community," *Downing, supra*, at 1238, may properly be viewed with skepticism.

The inquiry envisioned by Rule 702 is, we emphasize, a flexible one.[12] Its overarching subject is the scientific validity — and thus the evidentiary relevance and reliability — of the principles that underlie a proposed submission. The focus, of

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[12] A number of authorities have presented variations on the reliability approach, each with its own slightly different set of factors. *See, e.g., Downing*, 753 F.2d 1238-1239 (on which our discussion draws in part); 3 Weinstein & Berger P 702[03], pp. 702-41 to 702-42 (on which the Downing court in turn partially relied); McCormick, Scientific Evidence: Defining a New Approach to Admissibility, 67 Iowa L. Rev. 879, 911-912 (1982); and Symposium on Science and the Rules of Evidence, 99 F.R.D. 187, 231 (1983) (statement by Margaret Berger). To the extent that they focus on the reliability of evidence as ensured by the scientific validity of its underlying principles, all these versions may well have merit, although we express no opinion regarding any of their particular details.

course, must be solely on principles and methodology, not on the conclusions that they generate.

Throughout, a judge assessing a proffer of expert scientific testimony under Rule 702 should also be mindful of other applicable rules. Rule 703 provides that expert opinions based on otherwise inadmissible hearsay are to be admitted only if the facts or data are "of a type reasonably relied upon by experts in the particular field in forming opinions or inferences upon the subject." Rule 706 allows the court at its discretion to procure the assistance of an expert of its own choosing. Finally, Rule 403 permits the exclusion of relevant evidence "if its probative value is substantially outweighed by the danger of unfair prejudice, confusion of the issues, or misleading the jury . . . ." Judge Weinstein has explained: "Expert evidence can be both powerful and quite misleading because of the difficulty in evaluating it. Because of this risk, the judge in weighing possible prejudice against probative force under Rule 403 of the present rules exercises more control over experts than over lay witnesses." Weinstein, 138 F.R.D., at 632.

III

We conclude by briefly addressing what appear to be two underlying concerns of the parties and amici in this case. Respondent expresses apprehension that abandonment of "general acceptance" as the exclusive requirement for admission will result in a "free-for-all" in which befuddled juries are confounded by absurd and irrational pseudoscientific assertions. In this regard respondent seems to us to be overly pessimistic about the capabilities of the jury, and of the adversary system generally. Vigorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof are the traditional and appropriate means of attacking shaky but admissible evidence. *See Rock v. Arkansas*, 483 U.S. 44, 61, 97 L. Ed. 2d 37, 107 S. Ct. 2704 (1987). Additionally, in the event the trial court concludes that the scintilla of evidence presented supporting a position is insufficient to allow a reasonable juror to conclude that the position more likely than not is true, the court remains

free to direct a judgment, Fed. Rule Civ. Proc. 50 (a), and likewise to grant summary judgment, Fed. Rule Civ. Proc. 56. *Cf., e.g., Turpin v. Merrell Dow Pharmaceuticals, Inc.*, 959 F.2d 1349 (CA6) (holding that scientific evidence that provided foundation for expert testimony, viewed in the light most favorable to plaintiffs, was not sufficient to allow a jury to find it more probable than not that defendant caused plaintiff's injury), *cert. denied*, 506 U.S. ___ (1992); *Brock v. Merrell Dow Pharmaceuticals, Inc.*, 874 F.2d 307 (CA5 1989) (reversing judgment entered on jury verdict for plaintiffs because evidence regarding causation was insufficient), *modified*, 884 F.2d 166 (CA5 1989), *cert. denied*, 494 U.S. 1046 (1990); *Green* 680-681. These conventional devices, rather than wholesale exclusion under an uncompromising "general acceptance" test, are the appropriate safeguards where the basis of scientific testimony meets the standards of Rule 702.

Petitioners and, to a greater extent, their amici exhibit a different concern. They suggest that recognition of a screening role for the judge that allows for the exclusion of "invalid" evidence will sanction a stifling and repressive scientific orthodoxy and will be inimical to the search for truth. *See, e.g.*, Brief for Ronald Bayer *et al.* as *Amici Curiae*. It is true that open debate is an essential part of both legal and scientific analyses. Yet there are important differences between the quest for truth in the courtroom and the quest for truth in the laboratory. Scientific conclusions are subject to perpetual revision. Law, on the other hand, must resolve disputes finally and quickly. The scientific project is advanced by broad and wide-ranging consideration of a multitude of hypotheses, for those that are incorrect will eventually be shown to be so, and that in itself is an advance. Conjectures that are probably wrong are of little use, however, in the project of reaching a quick, final, and binding legal judgment — often of great consequence — about a particular set of events in the past. We recognize that in practice, a gatekeeping role for the judge, no matter how flexible, inevitably on occasion will prevent the jury from learning of authentic insights and innovations. That, nevertheless, is the balance that is struck by Rules of Evidence designed not for the exhaustive search for

cosmic understanding but for the particularized resolution of legal disputes.[13]

IV

To summarize: "general acceptance" is not a necessary precondition to the admissibility of scientific evidence under the Federal Rules of Evidence, but the Rules of Evidence — especially Rule 702 — do assign to the trial judge the task of ensuring that an expert's testimony both rests on a reliable foundation and is relevant to the task at hand. Pertinent evidence based on scientifically valid principles will satisfy those demands.

The inquiries of the District Court and the Court of Appeals focused almost exclusively on "general acceptance," as gauged by publication and the decisions of other courts. Accordingly, the judgment of the Court of Appeals is vacated and the case is remanded for further proceedings consistent with this opinion.

It is so ordered.

CHIEF JUSTICE REHNQUIST, with whom JUSTICE STEVENS joins, concurring in part and dissenting in part:

The petition for certiorari in this case presents two questions: first, whether the rule of *Frye v. United States*, 54 App. D.C. 46, 293 F. 1013 (1923), remains good law after the enactment of the Federal Rules of Evidence; and second, if *Frye* remains valid, whether it requires expert scientific testimony to have been subjected to a peer-review process in order to be admissible. The Court concludes, correctly in my view, that the

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[13] This is not to say that judicial interpretation, as opposed to adjudicative factfinding, does not share basic characteristics of the scientific endeavor: "The work of a judge is in one sense enduring and in another ephemeral. . . . In the endless process of testing and retesting, there is a constant rejection of the dross and a constant retention of whatever is pure and sound and fine." B. Cardozo, The Nature of the Judicial Process 178, 179 (1921).

Frye rule did not survive the enactment of the Federal Rules of Evidence, and I therefore join Parts I and II-A of its opinion. The second question presented in the petition for certiorari necessarily is mooted by this holding, but the Court nonetheless proceeds to construe Rules 702 and 703 very much in the abstract, and then offers some "general observations." *Ante*, at [A32].

"General observations" by this Court customarily carry great weight with lower federal courts, but the ones offered here suffer from the flaw common to most such observations — they are not applied to deciding whether or not particular testimony was or was not admissible, and therefore they tend to be not only general, but vague and abstract. This is particularly unfortunate in a case such as this, where the ultimate legal question depends on an appreciation of one or more bodies of knowledge not judicially noticeable, and subject to different interpretations in the briefs of the parties and their amici. Twenty-two amicus briefs have been filed in the case, and indeed the Court's opinion contains no less than 37 citations to amicus briefs and other secondary sources.

The various briefs filed in this case are markedly different from typical briefs, in that large parts of them do not deal with decided cases or statutory language — the sort of material we customarily interpret. Instead, they deal with definitions of scientific knowledge, scientific method, scientific validity, and peer review — in short, matters far afield from the expertise of judges. This is not to say that such materials are not useful or even necessary in deciding how Rule 703 should be applied; but it is to say that the unusual subject matter should cause us to proceed with great caution in deciding more than we have to, because our reach can so easily exceed our grasp.

But even if it were desirable to make "general observations" not necessary to decide the questions presented, I cannot subscribe to some of the observations made by the Court. In Part II-B, the Court concludes that reliability and relevancy are the touchstones of the admissibility of expert testimony. *Ante*, at [A28-31]. Federal Rule of Evidence 402 provides, as the Court points out, that "evidence which is not relevant is not admissi-

ble." But there is no similar reference in the Rule to "reliability." The Court constructs its argument by parsing the language "if scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue . . . an expert . . . may testify thereto . . . ." Fed. Rule Evid. 702. It stresses that the subject of the expert's testimony must be "scientific . . . knowledge," and points out that "scientific" "implies a grounding in the methods and procedures of science," and that the word "knowledge" "connotes more than subjective belief or unsupported speculation." *Ante*, at **[A29]**. From this it concludes that "scientific knowledge" must be "derived by the scientific method." *Ante*, at **[A29]**. Proposed testimony, we are told, must be supported by "appropriate validation." *Ante*, at **[A29]**. Indeed, in footnote 9, the Court decides that "in a case involving scientific evidence, evidentiary reliability will be based upon scientific validity." *Ante*, at **[A29** n.9**]**. (emphasis in original).

Questions arise simply from reading this part of the Court's opinion, and countless more questions will surely arise when hundreds of district judges try to apply its teaching to particular offers of expert testimony. Does all of this dicta apply to an expert seeking to testify on the basis of "technical or other specialized knowledge" — the other types of expert knowledge to which Rule 702 applies — or are the "general observations" limited only to "scientific knowledge"? What is the difference between scientific knowledge and technical knowledge; does Rule 702 actually contemplate that the phrase "scientific, technical, or other specialized knowledge" be broken down into numerous subspecies of expertise, or did its authors simply pick general descriptive language covering the sort of expert testimony which courts have customarily received? The Court speaks of its confidence that federal judges can make a "preliminary assessment of whether the reasoning or methodology underlying the testimony is scientifically valid and of whether that reasoning or methodology properly can be applied to the facts in issue." *Ante*, at **[A31-32]**. The Court then states that a "key question" to be answered in deciding whether something is "scientific knowledge" "will be whether it can be (and has been) tested." *Ante*, at

[A32]. Following this sentence are three quotations from treatises, which speak not only of empirical testing, but one of which states that "the criterion of the scientific status of a theory is its falsifiability, or refutability, or testability," *ante*, p. [A32].

I defer to no one in my confidence in federal judges; but I am at a loss to know what is meant when it is said that the scientific status of a theory depends on its "falsifiability," and I suspect some of them will be, too.

I do not doubt that Rule 702 confides to the judge some gatekeeping responsibility in deciding questions of the admissibility of proffered expert testimony. But I do not think it imposes on them either the obligation or the authority to become amateur scientists in order to perform that role. I think the Court would be far better advised in this case to decide only the questions presented, and to leave the further development of this important area of the law to future cases.

APPENDIX D

UNITED STATES COURT OF APPEALS
For the Ninth Circuit

No. 90-55397

WILLIAM DAUBERT; JOYCE DAUBERT, individually and as Guardians Ad Litem for JASON DAUBERT, a minor; ANITA DE YOUNG, individually, and As Guardian Ad Litem for ERIC SCHULLER,

Plaintiffs-Appellants,

v.

MERRELL DOW PHARMACEUTICALS, INC., a Delaware corporation,

Defendant-Appellee.

Appeal from the United States District Court
For the Southern District of California

(December 20, 1991)

Before: Alex Kozinski and Diarmuid F. O'Scannlain, Circuit Judges, and Stephen M. McNamee,* District Judge.

KOZINSKI, Circuit Judge:

Plaintiffs Jason Daubert and Eric Schuller suffer from limb reduction birth defects. They allege that these defects resulted

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* The Honorable Stephen M. McNamee, United States District Judge for the District of Arizona, sitting by designation.

from the fact that their mothers used Bendectin, a prescription anti-nausea drug, during pregnancy. The plaintiffs seek damages from the drug's manufacturer, defendant Merrell Dow Pharmaceuticals.

Plaintiffs' evidence of causation consisted primarily of expert opinion based on *in vitro* and *in vivo* animal tests, chemical structure analyses and the reanalysis of epidemiological studies. Among the contrary evidence proffered by Merrell Dow was the affidavit of a physician and epidemiologist who reviewed all of the available literature on the subject, which included more than 30 published studies involving over 130,000 patients, and concluded that no published epidemiological study had demonstrated a statistically significant association between Bendectin and birth defects. Plaintiffs do not challenge this summary of the published record.

The district court determined that plaintiffs could not meet their burden of proving that Bendectin caused Jason's and Eric's birth defects and granted Merrell Dow's motion for summary judgment. *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 727 F. Supp. 570 (S.D. Cal. 1989).

A. Expert opinion based on a scientific technique "is admissible if it is generally accepted as a reliable technique among the scientific community." *United States v. Solomon*, 753 F.2d 1522, 1526 (9th Cir. 1985) (citing *Frye v. United States*, 293 F. 1013, 1014 (D.C. Cir. 1923)). We impose this requirement because such evidence "creates a substantial danger of undue prejudice or of confusing the issues or of misleading the jury . . . because of its aura of special reliability and trustworthiness." *United States v. Amarel*, 488 F.2d 1148, 1152 (9th Cir. 1973); *see also* Learned Hand, *Historical and Practical Considerations Regarding Expert Testimony*, 15 HARV.L.REV. 40, 50-52 (1901). Moreover, whether expert opinion can satisfy this requirement is reviewed *de novo* by an appellate court, for "the answer to the question about the reliability of a scientific technique or process does not vary according to the circumstances of each case. It is therefore inappropriate to view this

threshold question of reliability as a matter within each trial judge's individual discretion." *Reed v. State*, 391 A.2d 364, 367 (Md. 1978); *see also United States v. Williams*, 583 F.2d 1194, 1197-1201 (2d Cir. 1978) (applying *de novo* review to the question of the general acceptance of a scientific technique), *cert. denied*, 439 U.S. 1117 (1979).

For expert opinion based on a given scientific methodology to be admissible, the methodology cannot diverge significantly from the procedures accepted by recognized authorities in the field. If it does so diverge, it cannot be shown to be "generally accepted as a reliable technique," *Solomon*, 753 F.2d at 1526, and a district court must exclude it. If such evidence is admitted and materially affects the verdict, a judgment supported by this evidence cannot stand. *See Lindsey v. United States*, 237 F.2d 893, 897-98 (9th Cir. 1956).

B. Whether Bendectin is responsible for limb reduction defects is not a new question in the federal courts. Four of our sister circuits have considered whether plaintiffs could establish such responsibility in the absence of critically analyzed epidemiological studies establishing a connection between the use of the drug and the birth defects. *DeLuca v. Merrell Dow Pharmaceuticals, Inc.*, 911 F.2d 941 (3d Cir. 1990); *Brock v. Merrell Dow Pharmaceuticals, Inc.*, 874 F.2d 307, *modified*, 884 F.2d 166 (5th Cir. 1989), *cert. denied*, 110 S. Ct. 1511 (1990); *Richardson v. Richardson-Merrell, Inc.*, 857 F.2d 823 (D.C. Cir. 1988), *cert. denied*, 110 S. Ct. 218 (1989); *Lynch v. Merrell-National Labs.*, 830 F.2d 1190 (1st Cir. 1987) (opinion by Noonan, J., sitting by designation). Three circuits have concluded that the plaintiffs could not establish such a link. Considering largely the same evidence presented to the district court below, these courts held that the animal and chemical studies were insufficient to establish a link between Bendectin and birth defects, *Brock*, 874 F.2d at 313-15; *Richardson*, 857 F.2d at 830; *Lynch*, 830 F.2d at 1194, in part because the plaintiffs' own experts acknowledged the need to verify such data with epidemiological evidence.

Brock, 874 F.2d at 314; *Richardson*, 857 F.2d at 830.[1] These courts were unwilling to allow plaintiffs to rely on reanalyses of epidemiological studies because these reanalyses had neither been published nor subjected to the rigors of peer review. They found the methodology particularly problematic in light of the massive weight of the original published studies supporting the defendant's position, all of which had undergone full scrutiny from the scientific community. *See Brock*, 874 F.2d at 312-13; *Richardson*, 857 F.2d at 831; *Lynch*, 830 F.2d at 1193-96; *see also Christophersen v. Allied-Signal Corp.*, 939 F.2d 1106, 1111 n.8 (5th Cir. 1991) (en banc).[2]

Plaintiffs argue that reanalysis is a generally accepted scientific technique, so it follows that their experts were basing their opinions on a permissible methodology. But the reanalysis of epidemiological studies is generally accepted by the scientific community only when it is subjected to verification and scrutiny

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[1] *Richardson* and *Lynch* held that expert testimony that Bendectin caused birth defects, based solely on animal and chemical tests and reanalyses of epidemiological studies, was inadmissible under Federal Rule of Evidence 703, and that therefore plaintiffs had failed to present evidence to support a jury verdict in their favor. 857 F.2d at 830-831; 830 F.2d at 1193-96. *Brock* did not hold that the plaintiffs' expert testimony was inadmissible, but did decide that it was insufficient to support the jury's verdict. 874 F.2d at 315.

[2] The Third Circuit has left open the possibility that expert testimony based on the reanalysis of epidemiological studies may be admissible if it can be shown to be reliable and not too likely to overwhelm, confuse or mislead the jury. *See DeLuca*, 911 F.2d at 955 (remanding case for district court to reconsider the admissibility of plaintiffs' expert testimony). Because the Third Circuit has specifically rejected the *Frye/Solomon* "generally accepted" standard, *United States v. Downing*, 753 F.2d 1224, 1236-37 (3d Cir. 1985), we find the court's analysis in *DeLuca* to be contrary to our established precedent and decline to follow it.

by others in the field. *See* Dore, *A Commentary on the Use of Epidemiological Evidence in Demonstrating Cause-in-Fact*, 7 HARV.ENV'L L.REV. 429, 438-39 (1983) (discussing requirements for original epidemiological studies). Plaintiffs' reanalyses do not comply with this standard; they were unpublished, not subjected to the normal peer review process, and generated solely for use in litigation.[3] It does not suffice that the expert's methodology meet *some* of the requirements imposed by the scientific community; it must meet *all* of the essential requirements. Selective borrowing from generally accepted scientific methodology does not satisfy *Solomon*'s rigorous standard.

C. *Lynch*, *Richardson* and *Brock* reflect a well-founded skepticism of the scientific value of the reanalysis methodology employed by plaintiffs' experts; they recognize that "the best test of certainty we have is good science — the science of publication, replication, and verification, the science of consensus and peer review." P. Huber, *Galileo's Revenge: Junk Science in the Courthouse*, 228 (1991). For the convincing reasons articulated by our sister circuits, we agree with the district court that the available animal and chemical studies, together with plaintiffs' expert reanalysis of epidemiological studies, provide insufficient foundation to allow admission of expert testimony to the effect that Bendectin caused plaintiffs' injuries. Accordingly, plaintiffs could not satisfy their burden of proving causation at trial. *See Christophersen*, 939 F.2d at 1109 ("When the contested evidence is essential to the cause of action and the trial court has excluded the evidence, we may decide the appeal . . . solely on the basis of the soundness of the evidentiary ruling. For if we

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[3] Scientific studies conducted in anticipation of litigation must be scrutinized much more carefully than studies conducted in the normal course of scientific inquiry. This added dose of skepticism is warranted, in part, because studies generated especially for use in litigation are less likely to have been exposed to the normal peer review process, which is one of the hallmarks of reliable scientific investigation. *See Brock*, 874 F.2d at 313; *Richardson*, 857 F.2d at 831 n.55; *Perry v. United States*, 755 F.2d 888, 892 (11th Cir. 1985).

uphold the exclusion of essential evidence, the [review of the summary judgment ruling] becomes academic.").

AFFIRMED.

APPENDIX E

IN THE UNITED STATES DISTRICT COURT FOR THE SOUTHERN DISTRICT OF CALIFORNIA

WILLIAM DAUBERT, et al., *Plaintiffs*,	)	
v.	)	
MERRELL DOW PHARMACEUTICALS, INC., et al., *Defendants*.	)	CIVIL NOS. 84-2013-G(IEG), 84-2929-G(IEG) (Consolidated)
MICHAEL SCHULLER et al., *Plaintiffs*,	)	
v.	)	
MERRELL DOW PHARMACEUTICALS, INC., et al., *Defendants*.	)	

MEMORANDUM DECISION AND ORDER

EARL B. GILLIAM, UNITED STATES DISTRICT JUDGE:

The defendant's motion for summary judgment was scheduled for hearing on October 6, 1989, in Courtroom 7 before the Honorable Earl B. Gilliam. Plaintiffs were represented by Mary Gillick and Barry Nace. George Berry, Robert Dickson and Pamela Yates appeared on behalf of defendant. Having considered the points and authorities and oral argument of counsel, the court issues this memorandum decision and order granting defendant's motion for summary judgment.

FACTS

This case involves personal injuries sustained by plaintiffs. Infant plaintiffs and their guardians ad litem seek damages from defendant for injuries (limb reduction birth defects) allegedly sustained as a result of the mothers' ingestion of Bendectin during pregnancy. Bendectin is a prescription pharmaceutical product previously manufactured by Merrell Dow, indicated solely for the treatment of nausea and vomiting during pregnancy. Defendant has moved for summary judgment, arguing that plaintiffs have failed to sustain their burden of establishing a genuine issue of material fact regarding causation.

DISCUSSION

Summary judgment is proper "after adequate time for discovery and upon motion, against a party who fails to make a showing sufficient to establish the existence of an element essential to that party's case, and on which that party will bear the burden of proof at trial. . . ." *Celotex Corp. v. Catrett*, 477 U.S. 317, 322 (1986). "[T]h[e] standard [for granting summary judgment] mirrors the standard for a directed verdict under Federal Rule of Civil Procedure 50(a). . . ." *Id.* at 323 (citing *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 250 (1986)).

In this case the defendant has moved for summary judgment. Plaintiffs, who have the burden of proof by a preponderance of the evidence, oppose the motion. The court must therefore determine "whether a fair-minded jury could return a verdict for the plaintiff [based] on the evidence presented." *Anderson v. Liberty Lobby, Inc.* 477 U.S. at 251-252. The court must view the evidence in a light most favorable to plaintiff, however, "[t]he evidence is insufficient if the strongest inference to be drawn in the plaintiff's favor is that defendant's negligence could *possibly* have been the cause of the accident." *Bieghler v. Kleppe*, 633 F.2d 531, 533 (9th Cir. 1980) (emphasis in original) (citing *Neely v. St. Paul Fire & Marine Insurance Co.*, 584 F.2d 341, 345 (9th Cir. 1978)). The plaintiff must show that defendant's negligence "was more probably than not the proximate cause of the accident" to defeat summary judgment and take the

issue to a jury. *Bieghler* at 533. The court should exclude inadmissible evidence objected to by either party prior to ruling upon the motion. *See, Hollingsworth Solderless Terminal Co., v. Turley* 622 F.2d 1324, 1335 (9th Cir. 1980).

Federal Rule of Evidence (FRE) 703, restricts the admissibility of scientific evidence. "A necessary predicate to the admission of scientific evidence is that the principle upon which it is based 'must be sufficiently established to have general acceptance in the field to which it belongs.'" *United States v. Kilgus*, 571 F.2d 508, 510 (9th Cir. 1978). Therefore, expert opinion not based on facts or data "of a type reasonably relied upon by experts in the particular field" is not helpful, but instead is confusing or misleading and should therefore be excluded. *See*, Fed.R.Evid. 403. *See also Barrel of Fun, Inc. v. State Farm Fire and Casualty Co.*, 739 F.2d 1028, 1033 (5th Cir. 1984) (excluding expert's opinion based on polygraph test). "Whether an expert's opinion has an adequate basis, and whether without it an evidentiary burden has been met, are matters of law for the court to decide." *Richardson v. Richardson-Merrell*, 857 F.2d 823, 829 (D.C.Cir. 1988), *cert. denied*, 107 L.Ed. 2d 171 (1989).

There are two schools of thought governing expert testimony in these Bendectin cases, and one seems to be prevailing in the federal courts. Unfortunately for the plaintiffs, the prevailing school of thought warrants summary judgment in this case.

The prevailing school is best exemplified by *Brock v. Merrell Dow Pharmaceuticals*, 874 F.2d 307 (5th Cir. 1989), *modified*, 884 F.2d 166 (5th Cir. 1989), *rehr'g denied, en banc*, 884 F.2d 167 (5th Cir. 1989) where the court held the following:

> We find, in this case, the Brocks' failure to present statistically significant epidemiological proof that Bendectin causes limb reduction defects to be fatal to their case.

Id. at 313. The court also noted:

> Hopefully, our decision will have the effect of encouraging district judges faced with medical and epidemiological proof

> in subsequent toxic tort cases to be especially vigilant in scrutinizing the basis, reasoning, and statistical significance of studies presented by both sides. However, we do not wish this case to stand as a bar to future Bendectin cases in the event that new and statistically significant studies emerge which would give a jury a firmer basis on which to determine the issue of causation.

Id. at 315. Several other cases are in accord with this reasoning. *See, Richardson v. Richardson-Merrell, supra*; *Lynch v. Merrell-National Laboratories*, 830 F.2d 1190 (1st Cir. 1987); *Hull v. Merrell Dow Pharmaceuticals, Inc.*, 700 F.Supp. 28 (S.D.Fla. 1988); *In Re Richardson-Merrell, Inc. "Bendectin" Products Liability Litigation*, 624 F.Supp. 1212 (S.D.Ohio 1985), *aff'd*, 857 F.2d 290 (6th Cir. 1988), *cert. denied* 109 S.Ct. 788 (1989); *Thompson v. Merrell Dow Pharmaceuticals, Inc.*, 229 N.J.Super. 230, 551 A.2d 177 (1988).

In medical cases like this one, courts must "critically evaluate the reasoning process by which the experts connect data to their conclusions in order for courts to consistently and rationally resolve the disputes before them." *Brock*, 874 F.2d at 310. Absent a scientific understanding of the cause of the birth defects at issue in Bendectin cases, causation may be shown only through reliance upon epidemiological evidence. *See, Richardson v. Richardson-Merrell*; *Lynch v. Merrell-National Laboratories*. *See also In Re Agent Orange Product Liability Lit.*, 611 F.Supp. 1223 (E.D.N.Y. 1985), *aff'd*, 818 F.2d 187 (2nd Cir. 1987) (stating that epidemiological studies were "the only useful studies having any bearing on causation" in Agent Orange cases).

In *Richardson*, Dr. Done, the plaintiff's expert, relied upon 1) chemical structure activity analysis, 2) *in vitro* (test tube) studies, 3) *in vivo* (animal teratology) studies, and 4) reanalysis of epidemiology studies. He used the results of these four types of studies to conclude that within a reasonable degree of certainty, Bendectin causes birth defects. The court concluded that Dr. Done's testimony lacked an adequate scientific basis:

> These three types of studies -- chemical, *in vitro*, and *in vivo* -- cannot furnish a sufficient foundation for a conclusion that Bendectin caused the birth defects at issue in this case. Studies of this kind singly or in combination are not capable of proving causation in human beings in the face of the overwhelming body of contradictory epidemiological evidence.

Richardson, 857 F.2d at 830. The court also rejected the reanalysis of the epidemiological studies:

> Dr. Done further admitted that no one who had published work on Bendectin had concluded that there was a statistically significant association between Bendectin and limb reduction defects. . . . Only by recalculating the data was Dr. Done able to obtain what he deems a statistically significant result. Moreover, the studies rejected by Dr. Done had been published in peer-reviewed scientific journals, while Dr. Done has neither published his recalculations nor offered them for review.

Id. at 831 (emphasis added).

The plaintiffs rely on *Oxendine v. Merrell Dow Pharmaceuticals, Inc.*, 506 A.2d 1100 (D.C.App. 1986) and other cases which basically give more deference to the expert's opinion. *Oxendine* is the leading Bendectin case in this regard, and the appellate court found that Dr. Done had a sufficient foundation for his testimony when he relied upon chemical analyses, animal studies, *in vitro* studies and recalculations of epidemiological studies:

> Dr. Alan Done, appellant's sole causation witness, had testified that no conclusion about Bendectin's effect on humans could be drawn from any of the four types of scientific data upon which he principally relied when each type was considered separately from the others. The [trial] court focused on this fact and concluded that if each type of data, viewed in isolation, was not sufficient to prove that Bendectin caused birth defects, then all of them taken

> together could not prove it either. In so doing, the trial court erred [by granting defendant's motion for J.N.O.V.].

Oxendine, 506 A.2d at 1104. The *Oxendine* court viewed the recalculations of epidemiological studies and the varying conclusions as involving a "classic battle of the experts." *Id.* at 1110. The court refused to find that plaintiffs had provided insufficient evidence to support the jury verdict solely because they had not provided a single original or recalculated epidemiological study which showed a statistically significant association between Bendectin and birth defects. *Id.* at 1107-10.

Oxendine is definitely in the minority camp. Although there appears to be no Ninth Circuit authority directly applicable to these Bendectin cases, this court must view the authority developed by three other federal circuit courts in *Brock*, *Lynch* and *Richardson* as highly persuasive.

In this case, the plaintiffs offer the opinion testimony of eight experts to establish that Bendectin is a teratogen (it causes limb reduction defects generally), and that Bendectin ingested by the mothers during pregnancy caused the limb reduction defects suffered by the infant Daubert and Schuller plaintiffs. Those experts are Dr. Adrian Gross, Dr. Stuart Newman, Dr. Alan K. Done, Dr. Shanna Swan, Dr. Jay Glasser, Dr. Wayne Snodgrass, Dr. Johannes Thiersch and Dr. John Palmer. Plaintiffs have submitted this testimony in the form of affidavits, deposition transcripts, and transcripts from previous trials.

Dr. Adrian Gross is a licensed and accredited veterinarian with experience in pathology and toxicology. *Ealy v. Richardson-Merrell* transcript, Exhibit 26 at pages 650-60. Dr. Gross would testify at trial that to within a reasonable degree of certainty Bendectin is a teratogen. Dr. Gross would base his opinion on animal studies which allegedly show a statistically significant association between Bendectin and doxylamine succinate (a component of Bendectin) and birth defects. *Id.* at pages 834-38.

Dr. Stuart Newman is a specialist in developmental biology. *Ealy* transcript, Exhibit 21 at pages 198-203; *Newman Affidavit* at pages 1-6. Dr. Newman would testify at trial that to within a reasonable degree of certainty "Bendectin is capable of interfering with the development of the limb in the human being and causing birth defects in the developing limb of the human being and that Bendectin is a human teratogen in the normal therapeutic dose." *Newman Affidavit* at page 9. Dr. Newman would base his opinion on *in vitro* studies and the pharmacology aspects of Bendectin. *Id.*

Dr. Alan Done is a medical doctor with specialties in pediatrics, clinical pharmacology and toxicology. *Oxendine v. Richard-Merrell* transcript, Exhibit 31 at page 3. Dr. Done's profferred testimony is unclear from the materials presented, but he apparently would testify that to a reasonable degree of certainty Bendectin is a teratogen. *Id.* at 854. Dr. Done apparently would base his opinion on analyses of the chemical structure and properties of doxylamine succinate animal studies *in vivo, in vitro* studies, and various informal and formal human studies, including epidemiological ones. *Id.* at 853.

Dr. Shanna Swan is an epidemiologist and biostatistician practicing in the field of reproductive epidemiology. *Ealy* transcript, Exhibit 12 at pages 3523-27. Dr. Swan would testify that to a reasonable degree of certainty, it is her opinion "that considering all available data that is provided in animal, *in vitro* and epidemiological studies, including the relative risks, the confidence limits and also the power of the studies, that it is more likely than not that Bendectin is, in fact, associated with limb reduction defects." *Swan Affidavit* at page 7. Dr. Swan would base her opinion on "the methodology that is generally and reasonably relied upon by epidemiologists to analyze, study and interpret data that has been collected, published and unpublished in trying to draw opinions concerning whether or not there is a cause and effect relationship between a drug and a birth defect." *Id.* at page 7-8.

Dr. Jay Glasser is a specialist in biostatistics, epidemiology and biometry. *Hill v. Merrell Dow* transcript, Exhibit 32 at pages 4-7; *Glasser Affidavit* at pages 1-4. Dr. Glasser would testify that "Bendectin is within a reasonable degree of epidemiological certainty associated with congenital disorders, including limb defects." *Glasser Affidavit* at page 7. Dr. Glasser would base his opinion on techniques that are generally and reasonably relied upon by biometrists, epidemiologists and biostatisticians. *Id.*

Dr. Wayne Snodgrass is an associate professor of pediatrics and pharmacology and toxicology. *Rudell v. Merrell Dow* transcript, Exhibit 20 at page 2. Dr. Snodgrass would testify that in his opinion Bendectin is a human teratogen. *Id.* at page 4. Dr. Snodgrass would base his opinion on results of various studies in several disciplines including pharmacology, toxicology, *in vitro* studies, animal studies and human studies. *Id.*

Dr. Johannes Thiersch is a specialist in pathology and pharmacology. *Thiersch Curriculum Vitae*, Exhibit 18. Dr. Thiersch would testify that the chemical composition and physiological activity of a drug are of great interest and importance in determining whether a drug is a teratogen. *Ealy v. Richardson-Merrell* transcript, Exhibit 22 at page 1596.

Dr. John Palmer is a professor of pharmacology. *Palmer Affidavit* at pages 1-4. Dr. Palmer would testify that in his opinion to a reasonable medical and scientific certainty Bendectin is a teratogen. *Id.* at page 7. Dr. Palmer would base his opinion on the pharmacological data, animal studies data, *in vitro* studies data, epidemiological data and other human data. *Id.* at pages 5-7. Dr. Palmer would also testify that he has examined the medical records of the plaintiff children and to a reasonable degree of medical certainty Bendectin was taken at a period of time such as to effect their development and it indeed caused their limb defects. *Id.* at pages 7-8.

The federal courts have held that epidemiological studies are the most reliable evidence of causation in this area. Accordingly, expert opinion which is not based on epidemiological evidence is

not admissible to establish causation because it lacks the sufficient foundation necessary under FRE 703. *See, Brock*, 874 F.2d at 311-15; *Richardson*, 857 F.2d at 829-32; *Lynch*, 830 F.2d at 1194. Therefore, expert testimony concluding that Bendectin causes limb reduction defects which is based upon *in vitro* generally studies, chemical structure analyses and animal studies is insufficient to take the issue to the jury. The plaintiffs' experts must be competent to testify that some epidemiological study or recalculation shows a statistically significant relationship between the ingestion of Bendectin and birth defects and that this study forms the basis of their opinion. *Id.* In this case, the plaintiffs have failed to live up to the *Brock* mandate to provide some epidemiological evidence to support their claim that Bendectin is a teratogen. *Brock*, 874 F.2d at 315.

The defendants have introduced evidence that no epidemiological study ever performed has concluded that the use of Bendectin by pregnant women has a statistically significant association to birth defects in those women's children. *Report on the Safety of Bendectin/Diclectin for Use in the Management of Nausea and Vomiting of Pregnancy*, Exhibit J, Defendant's Reply to Affidavits of Plaintiff's Experts Submitted in Opposition to Defendant's Motion for Summary Judgment, at page 2 ("Controlled studies involving over 130,000 patients have not demonstrated any reproducible or consistent association of birth defects with Bendectin exposure. In fact, the results of the epidemiological studies are just what one might expect of an agent without reproductive or teratogenic risks."). *See also Statement of Steven H. Lamm*, Exhibit A, Defendant's Memorandum of Points and Authorities in Support of its Motion for Summary Judgment on the Issue of Causation at page 1 (after reviewing the world's literature on Bendectin and human birth defects, the studies "showed no difference in the risk of birth defects between those infants whose mothers had taken Bendectin during the first trimester of pregnancy and those infants whose mothers had not"). The plaintiffs' experts agree that none of the *published* studies show a statistically significant association between the use of Bendectin and birth defects. *See, e.g., Hill v. Merrell Dow*

Deposition of Jay H. Glasser, Exhibit J, Defendant's Memorandum of Points and Authorities in Support of its Motion for Summary Judgment on the Issue of Causation at page 164.

The plaintiffs argue that the absence of statistically significant epidemiological studies does not disprove the fact that Bendectin causes limb reduction defects. *See, e.g.*, Plaintiffs' Opposition to Defendant's Motion for Summary Judgment at 20-27; *Affidavit of Shanna Helen Swan* at pages 4-6. However, this argument directly contradicts the holdings of *Brock, Richardson* and *Lynch*. *See, supra*. The plaintiffs have the burden of proof, and they must come forward with statistically significant epidemiological evidence. The plaintiffs claim that Dr. Gross performed a new epidemiological study on Bendectin, but this is false. He simply recalculated a previously published study and tried to show that there actually was a significant relation between Bendectin and birth defects. *Letter to Thomas H. Bleakley*, Exhibit 40. Dr. Gross' "study" was apparently never published or subjected to peer review, and nowhere does it state that Bendectin sales increased the relative risk of limb reduction defects to a level significantly above 1.0 with a confidence interval that did not include unity. Dr. Gross alleges that this "study" shows "a statistically significant association that is highly significant" (Affidavit at page 11), but his allegation and this evidence is insufficient to take this matter to a jury. *See, Brock*, 874 F.2d at 312-13. Similarly, Dr. Swan's unsupported allegation that the Jick data "statistically significantly associates Bendectin and limb defects" (Affidavit at page 7) is similarly insufficient.

The court feels that the strongest inference to be drawn for plaintiffs based on the epidemiological evidence is that Bendectin could *possibly* have caused plaintiffs' injuries, therefore summary judgment is proper against them. *See, Bieghler v. Kleppe, supra*, 633 F.2d at 533. The court finds that there are no genuine issues of material fact with respect to causation and finds for the defendant on all causes of action.

IT IS SO ORDERED.

Dated: November 1, 1989

APPENDIX F

UNITED STATES COURT OF APPEALS
For the Ninth Circuit

No. 90-55397

WILLIAM DAUBERT; JOYCE DAUBERT, individually and as Guardians Ad Litem for JASON DAUBERT, a minor; ANITA DE YOUNG, individually, and As Guardian Ad Litem for ERIC SCHULLER,

Plaintiffs-Appellants,

v.

MERRELL DOW PHARMACEUTICALS, INC., a Delaware corporation,

Defendant-Appellee.

ORDER

Filed April 8, 1992

Before: KOZINSKI and O'SCANNLAIN, Circuit Judges, and MCNAMEE,* District Judge.

The petition for rehearing is denied. The full court has been advised of the suggestion for rehearing en banc and no active judge has requested a vote. The suggestion for rehearing en banc is therefore rejected. Fed.R.App.P. 35(b).

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* The Honorable Stephen M. McNamee, United States District Judge for the District of Arizona, sitting by designation.

APPENDIX G

Statement of Steven H. Lamm, M.D., D.T.P.H., and curriculum vitae (Ex. A to Deft.'s Mot. for Summ. Judg.), filed Aug. 3, 1989

UNITED STATES DISTRICT COURT
For the Southern District of California

NO. 84-2013-G(I)

WILLIAM DAUBERT; JOYCE DAUBERT, individually and as Guardians Ad Litem for JASON DAUBERT, a minor,
Plaintiffs,

v.

MERRELL DOW PHARMACEUTICALS, INC., and DOES 1 through 50 inclusive,
Defendants.

NO. 84-2929-G(I)

MICHAEL SCHULLER, ANITA DE YOUNG, and ANITA DE YOUNG as Guardian Ad Litem for ERIC SCHULLER,
Plaintiffs,

v.

MERRELL DOW PHARMACEUTICALS, INC., and DOES I through XX., inclusive
Defendants.

STATEMENT OF STEVEN H. LAMM, M.D., DTPH

I am a physician and epidemiologist who specializes in assessing the magnitude of risk from exposures to various chemical

and biological substances. I am currently the president of Consultants in Epidemiology and Occupational Health, Inc. at 2428 Wisconsin Avenue, N.W., Washington, D.C. 20007. In this capacity, I evaluate the risks of various cancers and birth defects from specific exposures. I have attached hereto my curriculum vitae, which includes a bibliography of various medical articles that I have authored or co-authored.

I first became involved in the Bendectin litigation when asked by the Guardian *ad litem* for class B plaintiffs, Samuel H. Porter, esq. in the multidistrict litigation in Cincinnati, *In Re Richardson-Merrell, Inc. "Bendectin" Product Liability Litigation II*, MDL No. 486, to prepare a report for Judge Carl Rubin who had certified a class action in that litigation.

I was sought by the Guardian *ad litem* to prepare a report for Judge Rubin to assist him in identifying the characteristics of the class. Preparation of this report necessitated assessment of the magnitude of risk of birth defects from maternal ingestion of Bendectin. In order to do this, I reviewed the literature submitted to the court by plaintiffs' and defendant's experts. In the preparation of my preliminary report (October 15, 1984), I reviewed the world's literature on Bendectin and human birth defects, including all those articles relied upon by either the experts for the plaintiffs or the defendants. These studies included reports on over 130,000 newborn infants. In toto, they showed no difference in the risk of birth defects between those infants whose mothers had taken Bendectin during the first trimester of pregnancy and those infants whose mothers had not.

I next reviewed in a similar manner the literature on Bendectin and limb reduction birth defects. I found no association between Bendectin and the occurrence of limb reduction birth defects.

In addition to reviewing the published scientific literature, I reviewed the overall experience that American women concurrently had with birth defects and with Bendectin usage during the years 1970 to 1984. I found no relationship between the annual frequency of Bendectin usage and the annual occurrences of specific birth defects. As no birth defects showed a drop in frequency when there was a drop in the frequency of Bendectin use, I concluded that there was no evidence from this data that Bendectin usage had anything to do with birth defect rates.

Since the time of that report, I have continued to monitor the literature and data on birth defect rates and on Bendectin usage. My current conclusions are no different from my conclusion of 1984, which is that although approximately 3-4% of all human births exhibit some congenital malformations, the frequency is no greater for the infants of mothers who took Bendectin during the first trimester of pregnancy than for the infants of mothers who did not take Bendectin during the first trimester of pregnancy. Based on my review of the scientific literature, I conclude that maternal use of Bendectin during the first trimester of pregnancy is not a risk factor for human birth defects in general, for limb reduction defects specifically, or for any other particular human birth defect.

I declare under penalty of perjury that the foregoing is true and correct.

/s/
STEVEN H. LAMM, M.D., DTPH

Washington, D.C.

Subscribed and sworn to before me
this 1 day of August 1989.
[notarization omitted]

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***Education*:**

1973-1974	London School of Hygiene and Tropical Medicine London, England Diploma in Tropical Public Health (DTPH)
1972-1973	Albert Einstein College of Medicine New York, New York Residency-Pediatrics
1969-1970	Montreal Children's Hospital Montreal, Quebec, Canada Residency-Pediatrics Special Project: Electronmicroscopy of Heart Muscle
1968-1969	University of Oregon Medical School Hospital and Associated Clinics Internship-Rotating
1964-1968	University of Southern California School of Medicine Medical Doctorate (MD)
1963-1964	University of Southern California Graduate School Master of Science in Biophysics (MS) Nerve Action Potential Conduction

1961-1963 University of California, Los Angeles
Bachelor of Science in Chemistry
Radiation Chemistry

1959-1961 Reed College, Portland, Oregon

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1976-1977	Private Practice of Pediatrics Pleasant Hill, CA
1974-1976	Senior Epidemiologist Epidemiology Branch, National Institute of Child Health and Human Development National Institute of Health Bethesda, MD
1972-1975	Lecturer in International Health and Consultant in Family Planning Development Administrators Training Program University of Connecticut Hartford, CT
1971-1973	Medical Director, Middletown Free Clinic Middletown, CT
1970-1972	Epidemic Intelligence Service Officer from the Center for Disease Control Atlanta, GA Attached to the Connecticut State Department of Health, Department of Preventable Diseases and the Connecticut State Tumor Registry
1968	WHO/USPHS Smallpox Eradication Program Kaduna, Nigeria

***Consultant Activities*:**

1986	Consultant to the Halogenated Organics Subcommittee of Environmental Health Committee of the Science Advisory Board to the Environmental Protection Agency

1986	Senate Commerce Committee on Product Liability Hearing for the Committee on Commerce, Science and Transportation
1986	Department of Health and Human Services, Public Health Service, National Institute of Health on Small Business
1985	Consultant in Epidemiology (Gynecomastia in Haitians), U.S. Department of Justice
1985	Member, Epidemiology Study Section on small business incentive grants to National Institute of Health
1984	Consultant in Drug Effect Epidemiology (Teratology), U.S. Federal Court, Cincinnati, Ohio
1983	Consultant in Epidemiology, Office of Civil Rights, U.S. Department of Justice
1977	Consultant in Birth Defect Epidemiology, National Center for Health Statistics
1973	USAID Consultant in Family Planning Training for Korea, Thailand, Bangladesh, and Pakistan
1972	Vaccine Morbidity Studies in Amazonian Indians, Yale-PAHO
1971	Short-Term Consultant on Cholera to the Phillipines, World Health Organization

***Honors*:**

American Academy of Occupational Medicine, Fellow 1987
American Occupational Medicine Association, Fellow 1985
American College of Toxicology, Associate Member 1984
American College of Preventive Medicine, Fellow 1983
American College of Preventive Medicine
Occupational Medicine 1983
Preventive Medicine 1975
American College of Epidemiology, Charter Fellow 1982

American Academy of Pediatrics, Fellow 1976
American Board of Pediatrics, 1975
Royal Society of Tropical Medicine, Fellow 1974
Annual Prize of the Society for Epidemiologic Research, May 1972

Teaching Experience:

Annual Lectures:
Occupational Medicine, Epidemiology, Teratology
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1988	Chairman, AIDS in the Workplace Symposium, American Industrial Hygiene Conference
1985-Present	Chairman, Occupational Medicine Committee American Industrial Hygiene Association
1984-1985	Chairman, Occupational Epidemiology Committee American Industrial Hygiene Association
1976-1978	Past Secretary-Treasurer Society for Epidemiologic Research 2423 Tunlaw Road, N.W. Washington, DC 20007
1975	Chairman, Symposia on Bioethics in International Health, APHA, Chicago, IL

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***Editorial Positions*:**

American Industrial Hygiene Association Journal
American Journal of Public Health
American Journal of Epidemiology
Public Health Reports

***Memberships in Professional Societies*:**

1987-Present American Academy of Occupational Medicine
1987-Present International Commission on Occupational Health
1986-Present American Medical Association
1986-Present International Society of Regulatory Toxicology and Pharmacology
1984-Present Air Pollution Control Association

1984-Present	American College of Toxicology
1983-Present	American Occupational Medical Association
1983	American College of Preventive Medicine
1983-Present	American Conference of Governmental Industrial Hygienists, Inc.
1982-Present	American College of Epidemiology
1982-Present	American Public Health Association
1980-Present	American Industrial Hygiene Association
1976	American Academy of Pediatrics
1974	Royal Society of Tropical Medicine

Publications:

1. "Effects of Bilary Obstruction on Serum Amylase and Lipase Activity," Cucci, Hiyashi and Lamm, *Epatologia*, 12:829-36, September/October, 1966.
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20. "Reactions to Ruebella Vaccine and Persistence of Antibody in Virgin-Soil Populations After Vaccination and Wild-Virus-Induced Immunization," Lamm, *J. Infect. Dis.* 133(4):393-398, 1976.
21. "Time Trends in Cause-Specific Infant Mortality Rates — U.S.A., 1968-74," Lamm, *Am. J. Epidem.*, 106:234, 1977.
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Revised 10/4/88